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From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 9/23/2020 3:19:07 AM
To: Brodd, Lauren (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ba665dea08e54171b3d6890c2518ddb9-leponelm]
Subject: Fwd: Materials for September 23 ACTIV Partnership Leadership Team Teleconference TOMORROW MORNING
Attachments: 9.23 ACTIV Leadership Team Meeting 20200922 vFinal.pdf; ATT00001.htm; 2020-08-26_ACTIV_Leadership_Team_Meeting_vFinal.docx; ATT00002.htm; 2020-09-09_Executive_Committee_Meeting_Summary_FINAL.docx; ATT00003.htm

FYI

Ashley Parker, Ph.D.

Office of the Director | National Institutes of Health

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Begin forwarded message:

From: "Wholley, David (FNIH) [T]" (b) (6)
To: "Austin, Christopher (NIH/NCATS) [E]" (b) (6), "Bancel, Stephane"
< (b) (6) >, "Carter, Kara" (b) (6) >, "Cavaleri, Marco"
< (b) (6) >, "Cihlar, Tomas" (b) (6) >, "Collins, Francis
(NIH/OD) [E]" (b) (6) >, "Corey, Larry" (b) (6) >, "Culp, Michelle (NIH/OD)
[E]" (b) (6) >, "Disbrow, Gary (OS/ASPR/BARDA)" < (b) (6) >, "Dolsten,
Mikael" (b) (6) >, "Erbelding, Emily (NIH/NIAID) [E]" < (b) (6) >
"Erck, Stan" (b) (6) >, "Fauci, Anthony (NIH/NIAID) [E]" (b) (6) >, "Freire,
Maria (FNIH) [T]" (b) (6) >, "Gadbois, Ellen (NIH/OD) [E]" < (b) (6) >, "Gibbons,
Gary (NIH/NHLBI) [E]" < (b) (6) >, "Hudson, Thomas" < (b) (6) >
"James, Stephanie (FNIH) [T]" < (b) (6) >, "Johnson, Robert (OS/ASPR/BARDA)"
< (b) (6) >, "Kramer, Lynn" (b) (6) >, "Lane, Cliff (NIH/NIAID) [E]"
(b) (6) >, "Lepore, John" (b) (6) >, "Marks, Peter (FDA/CBER)"
< (b) (6) >, "Marston, Hilary (NIH/NIAID) [E]" < (b) (6) >, "Mascola,
John (NIH/VRC) [E]" (b) (6) >, "Meeker, David" (b) (6) >, "Menetski,
Joseph (FNIH) [T]" < (b) (6) >, "Messonnier, Nancy (CDC/DDID/NCIRD/OD)"
< (b) (6) >, "Pandya, Hitesh" < (b) (6) >, "Pangalos, Mene"
< (b) (6) >, "Pao, William" (b) (6) >, "Parker, Ashley
(NIH/OD) [E]" (b) (6) >, "Paul, Steve" (b) (6) >, "Perlmutter, Roger"
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(b) (6) >, "Rachel Ramoni" (b) (6) >, "Rasi, Guido"
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(b) (6) >, "Rouse, Doris" (b) (6) >, "Santos, Michael (FNIH) [T]"
(b) (6) >, "Skovronsky, Daniel" (b) (6) >, "Stein, Peter (FDA/CDER)"
(b) (6) >, "Stoffels, Paul" (b) (6) >, "Tabak, Lawrence (NIH/OD) [E]"
(b) (6) >, "Talley, Michael" (b) (6) >, "Tsai, John"
(b) (6) >, "Vessey, Rupert" < (b) (6) >, "Virgin, Skip" (b) (6)
"Wholley, David (FNIH) [T]" (b) (6) >, "Woodcock, Janet (FDA/CDER)"
< (b) (6) >, "Young, John" (b) (6) >, "Colvis, Christine
(NIH/NCATS) [E]" (b) (6) >, "Desrosiers, Betsy" (b) (6) >
"Eric Hughes" (b) (6) >, "Jansen, Kathrin" (b) (6) >, "Kurilla,
Michael (NIH/NCATS) [E]" (b) (6) >, "Lowy, Douglas (NCI)" (b) (6) >, "Read,
Sarah (NIH/NIAID) [E]" (b) (6) >, "Young, John" (b) (6) >

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"Bugin, Kevin (FDA/CDER)"

Cc: "Anderson, James (NIH/OD) [E]" (b) (6), "Austin, Christopher (NIH/NCATS) [E]"
(b) (6) >, "Burklow, John (NIH/OD) [E]" < (b) (6) >, "Carlucci, Dana"
< (b) (6) >, "Castillejos, Carlos" (b) (6), "Culp, Michelle
(NIH/OD) [E]" < (b) (6), "FNIH Central Account" (b) (6) >, "Hallett,
Adrienne (NIH/OD) [E]" (b) (6) "Myles, Renate (NIH/OD) [E]"
(b) (6) >, "Parker, Ashley (NIH/OD) [E]" < (b) (6) "Gorman, Greta (FNIH)
[T]" (b) (6) >, "Hallett, Adrienne (NIH/OD) [E]" (b) (6), "Meltzer,
Abbey (FNIH) [T]" (b) (6) "Wolinetz, Carrie (NIH/OD) [E]" (b) (6),
"Adam, Stacey (FNIH) [T]" < (b) (6) >, "Alvarez, Rosa Maria" (b) (6),
"Margaret Anderson" (b) (6) >, "Appell, Evan" (b) (6) >, "Chen,
Helen Q." (b) (6) >, "Elsaid, Olivia" (b) (6) >, "Gonzalez, Nina"
(b) (6), "Hawk, Harrison" (b) (6) "Mendelson, Jesse"
, "Menetski, Joseph (FNIH) [T]" < (b) (6) "Santos, Michael
(FNIH) [T]" (b) (6) "Stratton, Benjamin" < (b) (6) "btolman"
(b) (6) >, "Tountas, Karen (FNIH) [T]" (b) (6) "Wachtel, Jonathan"
(b) (6) "Wholley, David (FNIH) [T]" < (b) (6) "Melencio, Cheryl (FNIH)
[T]" < (b) (6)

Subject: Materials for September 23 ACTIV Partnership Leadership Team Teleconference TOMORROW MORNING

Dear Colleagues:

Please see attached the PowerPoint slides, including the agenda, for our meeting (via Zoom) from **9:00 – 10:00 AM Eastern U.S. time tomorrow**, Wednesday September 23. I have also attached notes from our August 26 Leadership Team meeting as well as our last ACTIV EC meeting on September 9.

The Zoom meeting information is:

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Please let Joe Menetski or Cheryl Melencio here at FNIH (copied) know if you are having any problems connecting. I look forward to a productive meeting.

Regards,

David

David Wholley
Senior Vice-President, Research Partnerships
Foundation for the National Institutes of Health

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From: Mascola, John (NIH/VRC) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7F78B40A596B4CA4A2850A429D1AE3F2-JMASCOLA]
Sent: 5/14/2020 1:02:32 PM
To: Marks, Peter (FDA/CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b2e527dbda2b4a86b8d72f06b813d471-MarksP.fda]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]
CC: Fauci, Anthony (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=df38103d75134f658ae2d356f0396b94-afauci]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]
Subject: RE: ChAdOx1

Francis - we did make good progress on ACTIV Vaccine WG. Yesterday on the vaccine clinical trials subgroup, we presented the harmonized protocol approach and high level details of phase 3 design. There was good input on both and general agreement, with some useful recommendations on efficient ways to conduct phase 3.

One issues is that the Pfizer representative on the subgroup, both Kathrin Jansen (who is co-chair of Vaccines WG), and Bill Gruber (Pfizer Senior VP for R&D) – took turns articulating their view that large Pharma companies like theirs prefer not to work with USG and it would just slow them down. When we asked for suggestions for DSMB, Kathrin said she did not agree that we should ask for nominations – because this issue required more discussion – mainly because Pfizer has no interest in this. Doug Lowy was on the call, so may be useful to get his perspective.

John

From: Marks, Peter <(b) (6)>
Sent: Thursday, May 14, 2020 6:23 AM
To: Collins, Francis (NIH/OD) [E] <(b) (6)> Mascola, John (NIH/VRC) [E] <(b) (6)> Lane, Cliff (NIH/NIAID) [E] <(b) (6)>
Cc: Fauci, Anthony (NIH/NIAID) [E] <(b) (6)> Wholley, David (FNIH) [T] <(b) (6)> Tabak, Lawrence (NIH/OD) [E] <(b) (6)> Parker, Ashley (NIH/OD) [E] <(b) (6)>
Subject: RE: ChAdOx1

Dear Francis,

We had made good progress with the Oxford AZ team on the clinical end before the contracting period began. From my last conversation with the AZ clinical team they were on board with the USG concept of a large phase 3 trial, potentially as part of a master protocol if the timing was right. Their major issue was getting moving rapidly.

Among other things, Tony, John and I discussed the concept that (b) (5)
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Later today I will be speaking with John again about this merged concept. After giving it very careful consideration, though it certainly involves significant extra work in protocol development and logistic planning, (b) (5)

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(b) (5) Happy to discuss further.

Best Regards,
Peter

From: Collins, Francis (NIH/OD) [E] (b) (6)

Sent: Thursday, May 14, 2020 5:38 AM

To: Mascola, John R (NIH) (b) (6) Lane, Henry C (NIH) <(b) (6)> Marks, Peter (b) (6) >

Cc: Fauci, Anthony S (NIH) <(b) (6)>; Wholley, David N (NIH) (b) (6); Tabak, Lawrence A (NIH) (b) (6) >; Parker, Ashley S (NIH) (b) (6)

Subject: ChAdOx1

Gentlemen:

I need to know the update on where we are with Oxford, A-Z, and ChAdOx1. I see there's a BARDA WebEx at 5 pm, and I have a rescheduled phone call this morning with John Bell. I'd like to be as useful as possible in making a plan that includes this vaccine program as part of the harmonized master protocol. Advice about how to use the call with John Bell most effectively would be most welcome!

And did the Vaccines WG make good progress yesterday on the details of the harmonized master protocol? Did they agree in principle to a single DSMB?

Thanks, Francis

From: Tountas, Karen (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=40C04FEF6F1E46F5B750753CD5A14F93-TOUNTASKH]
Sent: 5/6/2020 7:29:07 PM
To: Bascles, Lionel [(b) (6)] Cohen, Myron [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2141b9e28c1a421fb3c1c4f75dd4c457-myron_cohen]; Corey, Larry [(b) (6)] Victoria Davey [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c8291f38ec342f895243c0617e115ec-victoria.da]; Desrosiers, Betsy [(b) (6)] Dickens, Jim (NIH/NCATS) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12591c90404e46caba73079cf4a5e2ea-dickensj]; Doroshov, James (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a1d0fb9f055940c39b387cae2485faa6-doroshovj]; Garner, Carlos [(b) (6)] Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Nayak, Seema (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=51d5ee6848004578b5bf9c808eca8f6f-nayaksu]; Payton, Manizhe (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=81d1c1824bfa438a94da81520a8bca90-paytonma]; Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Resnansky, Laura [(b) (6)] Sizemore, Christine (NIH/FIC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=05494833e0fc47a9acac194cd338b201-csizemore]; Srinivasan, Badhri [(b) (6)] Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Vincent, Mike [(b) (6)] Wachtel, Jonathan [(b) (6)]
CC: Criffield, Robin [(b) (6)] Hamilton, Nancy [(b) (6)] Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Minnich, Beth [(b) (6)]; Mueller-Reichenstein, Petra [(b) (6)] Quadros, Nora [(b) (6)] Katz, Rebecca (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8e2b174d9bf748e9aa5ed901b4c5a3d9-katzrd]; Hill, Zoe (NIH/NHLBI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a19ee51dca2a443d883a15e025d6e1e0-hillzs]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; Anderson, Margaret [(b) (6)] Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Carluccio, Dana [(b) (6)] Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Heaton, Penny [(b) (6)] James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Li, Rose [(b) (6)] Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Tuveson, Nancy [(b) (6)] Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hughes, Eric [(b) (6)] Jansen, Kathrin [(b) (6)] Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Young, John [(b) (6)]

Subject: Summary and action items - CT Capacity WG meeting #5
Attachments: Clinical_Trial_Capacity_Working_Group_Meeting #6_Summary_Final.pdf

Dear Clinical Trial Capacity Working Group Members,

Attached is the summary and action items for meeting #6 (May 5, 2020) of the full working group. The next full working group meeting is scheduled for Friday, May 8 at 9 am eastern time USA.

Best regards,
Karen

Karen H. Tountas, PhD
Scientific Program Manager
Foundation for the National Institutes of Health
(b) (6) | fnih.org
11400 Rockville Pike, Suite 600, North Bethesda, MD 20852



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Sent: 4/14/2020 1:24:31 PM
To: Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; Collins, Sylva (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylva.Coli]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Mark Eisner [(b) (6) Keith Gottesdiener [(b) (6) Eric Hughes [(b) (6) LaVange, Lisa M [(b) (6) Elliott Levy [(b) (6) Sandeep Menon [(b) (6) Amanda Peppercorn [(b) (6) Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Amanda Peppercorn [(b) (6)
CC: Mary Biggs [(b) (6) Demarcus [(b) (6) Macone, Erin [erinm@amgen.com]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [(b) (6) Elizabeth Kim [(b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Rose Li Central Account [(b) (6) Lucas Smalldon [(b) (6) Butcher, Tina [(b) (6)
Subject: ACTIV TX-Clinical WG Master Protocol Subgroup -1st Meeting
Location: [https://zoom.us/j/ \(b\) \(6\)](https://zoom.us/j/ (b) (6))
Start: 4/15/2020 5:30:00 PM
End: 4/15/2020 6:30:00 PM
Show Time As: Tentative

Required Attendees: Bozzette, Sam (NIH/NCATS) [E]; Joan Butterson; Collins, Sylva (FDA/CDER); Judy Currier; R. Angelo Declaro; Mark Eisner; Keith Gottesdiener; Eric Hughes; Lisa LaVange; Elliott Levy; Sandeep Menon; Amanda Peppercorn; Proschan, Michael (NIH/NIAID) [E]; Read, Sarah (NIH/NIAID) [E]; Amanda Peppercorn
Optional Attendees: Mary Biggs; Demarcus; Macone, Erin; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley (NIH/OD) [E]; Rose Li Central Account; Lucas Smalldon; Butcher, Tina

Dear ACTIV Therapeutics-Clinical WG Master Protocol Subgroup Members,

Thank you for your interest and participation in the Master Protocol sub-group. We are appreciative of your time and look forward to a focused discussion on the development of COVID-19 Master Protocols.

Our first meeting will take place today, Wednesday April 15th from 1:30pm-2:30pm ET. Dial-in instructions are below, similar to the zoom call on Monday. We wanted to notify you promptly of the meeting time and will follow up with an agenda and any necessary materials prior to the call.

Please note that this is not a fixed timeslot for upcoming sub-group meetings. After this first sub-group meeting, we will send out a scheduling link to coordinate the best time for sub group meetings moving forward.

Kind regards,
Stacey, on behalf of the ACTIV TX-Clinical WG

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 4/30/2020 12:16:16 AM
To: Eric Hughes [(b) (6)]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Ruxandra Draghia-Akli [(b) (6) .com]; Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Naimish Patel [(b) (6)]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Young, John [(b) (6)]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Poole, Mike [(b) (6)]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Vincent, Michael [(b) (6)]; Keith Gottesdiener [(b) (6)]; Elliott Levy [(b) (6)]; Wung, Peter /US [(b) (6)]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Carlos O Garner [(b) (6)]
CC: Elizabeth Kim [(b) (6)]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Alvarez, Rosa Maria [(b) (6)]; Salathin, Carla [(b) (6)]; (b) (6) ; (b) (6) ; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Lucas Smalldon [(b) (6)]; Walker, Paula (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fbe81b9b832e40acbf5fd03bcfd32930-walkerp1]; Ward, Jackie (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4114c7d13389454f89fe3411cb3a834f-wardjam]
Subject: Materials for ACTIV Therapeutics-Clinical Agent Prioritization Subgroup Meeting #5
Attachments: 2020-04-28_TX_Clinical_WG_Agent_Prioritization_Sub-WG_Summary.pdf; ACTIV Therapeutics Clinical_Agent Prioritization Sub-Group Meeting Agenda_04302020.pdf

Dear TX-Clinical Agent Prioritization Subgroup,

Thank you all for all the hard work you all are doing right now for the agent scoring. I appreciate all the information sharing that has been happening today to allow others to see the compound information you have found. I look forward chatting with you tomorrow to address any questions you may need addressed before our discussion of the results on Friday.

For reference tomorrow, please find attached the summary from yesterday's meeting and the agenda for tomorrow's meeting.

Thanks,

Stacey

Stacey J. Adam, PhD
Director, Cancer

APAR0000005617-2515757

Research Partnerships

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To: Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetski.jp]; Hild, Sheri (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=edd7f1939fb94be3bf063f925ac15f02-hildsa]; (b) (6) : (b) (6) (b) (6) (b) (6) (b) (6) Baric, Ralph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.email]; (b) (6) Ottinger, Elizabeth (NIH/NCATS) [E] [(b) (6) Colvis, Christine (NIH/NCATS) [E] [(b) (6) Hewitt, Judith (NIH/NIAID) [E] (b) (6) Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda]; (b) (6) (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Tomas Cihlar [(b) (6) Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA) (b) (6) (b) (6) (b) (6) (b) (6) Rao, Srinivas [(b) (6) (b) (6)

CC: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabcd42247548e596778304f781f-austinc]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy [(b) (6) Hughes, Eric [(b) (6) Jansen, Kathrin (b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Alvarez, Rosa Maria [(b) (6) Kim, Elizabeth [(b) (6) Tolman, Brett [(b) (6) Wachtel, Jonathan (b) (6) Prabhavathi Fernandes [(b) (6) Diamond, Michael [(b) (6) Rose Li [(b) (6) Dana Carluccio [(b) (6) Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagoses]; Jonson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Gonzalez, Nina [(b) (6) Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Rodriguez, Robin D [(b) (6) Dave Frankowski [(b) (6) Baric, Toni C

(b) (6) ; Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; Florence, Clint (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Nancy Haigwood [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=03d589f440d84691ac0a530e4ba6ceb5-haigwoon.oh]; Stratton, Benjamin [(b) (6) Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]

Start: 6/3/2020 2:00:00 PM

End: 6/3/2020 3:00:00 PM

Recurrence: (none)

Required Attendees: (b) (6) Hild, Sheri (NIH/OD) [E]; (b) (6) (b) (6)
(b) (6) (b) (6) (b) (6) (b) (6)
(b) (6) (b) (6) (b) (6) (b) (6)
(b) (6) ; (b) (6) (b) (6) (b) (6) (b) (6)
(b) (6) Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E];
(b) (6) Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas; Qashu, Felicia (NIH/OD) [E];
Tomas Cihlar; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA)
Optional Attendees: Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Diamond, Michael; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski; Baric, Toni C; Lowy, Douglas (NIH/NCI) [E]; Florence, Clint (NIH/NIAID) [E]; Nancy Haigwood; Stratton, Benjamin; Gadbois, Ellen (NIH/OD) [E]

To: Bozzette, Sam (NIH/NCATS) [E] [(b) (6) Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4];
 Butterson, Joan [(b) (6) De Claro, R. Angelo (FDA/CDER) [(b) (6)];
 Draghia-Akli, Ruxandra [(b) (6) Gottesdiener, Keith [(b) (6) Eric Hughes
 [(b) (6) Judy Currier [(b) (6) Kim, Elizabeth [(b) (6)
 LaVange, Lisa (b) (6) Mellors, John W [(b) (6)]; Menon, Sandeep
 [(b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative
 Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Patel, Naimish
 [(b) (6) Peppercorn, Amanda [(b) (6) Poole, Mike
 [(b) (6) Proschan, Michael (NIH/NIAID) [E] [(b) (6) Read, Sarah
 (NIH/NIAID) [E] [(b) (6) Santos, Michael (FNIH) [T] [(b) (6) Shen, Yuan Li (FDA/CDER)
 [(b) (6) Stein, Peter (FDA/CDER) [(b) (6) Wholley, David (FNIH) [T]
 [(b) (6) Buchman, Tim (OS/ASPR/BARDA) (CTR) [(b) (6) Collins, Sylva (FDA/CDER)
 [(b) (6) Amanda Peppercorn [(b) (6) Higgs, Elizabeth (NIH/NIAID)
 [E] [(b) (6) Koroshetz, Walter (NIH/NINDS) [E] [(b) (6) Timothy Burgess
 [(b) (6) Reineck, Lora (NIH/NHLBI) [E] [lora. (b) (6) Aggarwal, Neil (NIH/NHLBI) [E]
 [(b) (6) Rosenberg, Yves (NIH/NHLBI) [E] (b) (6) ; Goff, David (NIH/NHLBI) [E]
 (b) (6)]; Brown, Jeremy (NIH/NINDS) [E] [(b) (6) Gadbois, Ellen (NIH/OD) [E]
 [(b) (6)]; Culp, Michelle (NIH/OD) [E] (b) (6) ; Jacqueline Kirchner
 [(b) (6) Beigel, John (NIH) [E] [(b) (6) .gov]; Phillips, L Revell CIV DTRA
 RD (USA) [(b) (6) Petrovick, Martha - 0449 - MITLL [(b) (6)
 (b) (6) Sizemore, Christine (NIH/FIC) [E] [(b) (6) Larry Tsai
 (b) (6) Wung, Peter K [(b) (6) Garner, Carl [(b) (6)
 Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Levy, Elliot
 [(b) (6)
CC: Colvis, Christine (NIH/NCATS) [E] [(b) (6)]; Jansen, Kathrin [(b) (6) Lowy,
 Douglas (NCI) [(b) (6)]; Young, John [(b) (6) Biggs, Mary [(b) (6)
 Butcher, Tina [(b) (6) Demarcus [(b) (6) Maccone, Erin
 [(b) (6) Melencio, Cheryl (FNIH) [T] [(b) (6) Salathin, Carla
 [(b) (6) Menetski, Joseph (FNIH) [T] [(b) (6) Dana Carluccio
 [(b) (6) Rose Li Central Account [(b) (6) Lucas Smalldon
 [(b) (6) (b) (6) Mollica, Linda /US
 [(b) (6) Qashu, Felicia (NIH/OD) [E] [(b) (6)]; Patterson, Amy (NIH/NHLBI) [E]
 [(b) (6) Rubin, Daniel B. (FDA/CDER) [(b) (6) Marston, Hilary (NIH/NIAID) [E]
 [(b) (6) Chen, Helen Q. [(b) (6) Hoots, W. Keith (NIH/NHLBI) [E]
 [(b) (6) Groesch, Mary (NIH/NHLBI) [E] [(b) (6) Shipp, Allan (NIH/NHLBI) [E]
 (b) (6) Kindzelski, Andrei (NIH/NHLBI) [E] [(b) (6) Hone, David M (Dave) CIV
 DTRA J9 (USA) (b) (6) Reisler, Ronald B CTR USARMY DOD JPEO CBRND (USA)
 [(b) (6) Walker, Paula (NIH/NINDS) [E] [(b) (6) Sorosa, Alex David
 [(b) (6) Lumsden, Joanne (NIH/NCATS) [C] [(b) (6) Lerner, Andrea (NIH/NIAID)
 [E] (b) (6) Embry, Alan (NIH/NIAID) [E] [(b) (6) Dally, Nicolle
 [(b) (6)

Start: 4/22/2021 5:00:00 PM
End: 4/22/2021 6:00:00 PM

Recurrence: (none)

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 5/14/2020 2:33:58 PM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
Subject: RE: JAMA Viewpoint on ACTIV: please review

Has not gone out yet but I've placed everyone's email in the bcc line except for Renate, Abbey, and you. Figured FNIH would want to be looped in to those responses as well?

From: Wholley, David (FNIH) [T] <(b) (6)>
Sent: Thursday, May 14, 2020 10:29 AM
To: Parker, Ashley (NIH/OD) [E] <(b) (6)>
Subject: RE: JAMA Viewpoint on ACTIV: please review

This was sent as a .bcc yes?

From: Parker, Ashley (NIH/OD) [E] <(b) (6)>
Sent: Thursday, May 14, 2020 10:16 AM
To: Collins, Francis (NIH/OD) [E] <(b) (6)>; Myles, Renate (NIH/OD) [E] <(b) (6)> Kolberg, Rebecca (NIH/OD) [E] <(b) (6)>
Cc: Burklow, John (NIH/OD) [E] <(b) (6)>; Tabak, Lawrence (NIH/OD) [E] <(b) (6)>
Wholley, David (FNIH) [T] <(b) (6)>; Melencio, Cheryl (FNIH) [T] <(b) (6)>
Subject: RE: JAMA Viewpoint on ACTIV: please review

Hi Francis,

David forwarded the emails this morning. Please see below to make it easy to send.

I've pasted a slightly revised draft email OCPL provided (to also cc Renate, Abbey and David?). Renate – there are a few new members working group members, we can work together to update the list.

To:
Cc: Myles, Renate (NIH/OD) [E] <(b) (6)>; Meltzer, Abbey (FNIH) [T] <(b) (6)> Wholley, David (FNIH) [T] <(b) (6)>
Bcc: Stoffels, Paul <(b) (6)>; Fauci, Anthony (NIH/NIAID) [E] <(b) (6)> Gibbons, Gary (NIH/NHLBI) [E] <(b) (6)> Pao, William <(b) (6)> Woodcock, Janet (FDA/CDER) <(b) (6)> Arvin, Ann <aarvin@stanford.edu>; Buchbinder, Susan <(b) (6)> Corey, Larry <(b) (6)> Davis, Mark <(b) (6)> Emini, Emilio <(b) (6)> Hanon, Emmanuel <(b) (6)> Haynes, Barton <(b) (6)> Hotez, Peter <(b) (6)> Jansen, Kathrin <(b) (6)> Lanzavecchia, Antonio <(b) (6)> Lowy, Douglas (NIH/NCI) [E] <(b) (6)> Marks, Peter (FDA/CBER) <(b) (6)> Mascola, John <(b) (6)> Messonnier, Nancy (CDC/DDID/NCIRD/OD) <(b) (6)> Offit, Paul <(b) (6)> Parker, Ashley (NIH/OD) [E] <(b) (6)> Santos, Michael (FNIH) [T] <(b) (6)> Santos, Nancy <(b) (6)> Schuitemaker, Hanneke <(b) (6)> Tartaglia, Jim <(b) (6)> Tolman, Brett <(b) (6)> Zaks, Tal <(b) (6)> Qashu, Felicia (NIH/OD) [E] <(b) (6)> Michael, Nelson, <(b) (6)> Adam, Stacey (FNIH) [T] <(b) (6)> Bascles, Lionel <(b) (6)> Cohen, Myron <(b) (6)> Corey, Larry <(b) (6)> Desrosiers, Betsy <(b) (6)> Dickens, Jim (NIH/NCATS) [C] <(b) (6)>

Doroshow, James (NIH/NCI) [E] < (b) (6) Goff, David (NIH/NHLBI) [E] < (b) (6) Heaton,
 Penny (b) (6) >; Kurilla, Mike (b) (6) >; Nayak, Seema (NIH/NIAID) [E]
 (b) (6) >; Parker, Ashley (NIH/OD) [E] (b) (6) >; Payton, Manzine
 (b) (6) >; Resnansky, Laura (b) (6) Srinivasan, Badhri
 < (b) (6) Stein, Peter (FDA/CDER) (b) (6) Karen (FNIH) [T]
 (b) (6) Vincent, Mike (b) (6) Wachtel, Jonathan (b) (6)
 Woodcock, Janet (FDA/CDER) (b) (6) Sizemore, Christine
 (NIH/FIC) [E] (b) (6) Victoria Davey (b) (6) >; Qashu, Felicia (NIH/OD) [E]
 (b) (6) >; Weinmann, < (b) (6) Mensah, (b) (6)
 Adam, Stacey (FNIH) [T] (b) (6) ; Bozzette, Sam (NIH/NCATS) [E] (b) (6) Buchman, Tim
 (OS/ASPR/BARDA) (CTR) (b) (6) >; Butters, Joan (b) (6) Currier, Judy
 (b) (6) De Claro, R. Angelo (FDA/CDER) (b) (6) >; Draghia-Akli, Ruxandra
 (b) >; Eisner, Mark (b) (6) >; Garner,
 Carlos < (b) (6) > Gottesdiener, Keith (b) (6) Hughes, Eric
 (b) (6) Kim, Elizabeth <el (b) (6) LaVange, Lisa < (b) (6) Levy, Elliot
 (b) (6) Mellors, John < (b) (6) >; Menon, Sandeep (b) (6) >; Parker,
 Ashley (NIH/OD) [E] < (b) (6) Patel, Naimish (b) (6) >; Peppercorn, Amanda
 < (b) (6) Poole, Mike <M (b) (6) Proschan, Michael
 (b) (6) >; Read, Sarah (b) (6) >; Santos, Michael (FNIH) [T] (b) (6) >Shen,
 Yuan Li (FDA/CDER) (b) (6) Stein, Peter (FDA/CDER) (b) (6)
 ≤ (b) (6) Koroshetz, Walter < (b) (6) Farley, John < (b) (6)
 (b) (6) Qashu, Felicia (b) (6) Burgess,
 Timothy (b) (6) Reineck, Lora < (b) (6) Aggarwal, Neil (b) (6)

Subject: ACTION: Making your ACTIV Participation Public

Dear Colleagues:

NIH would like to launch an ACTIV webpage to provide stakeholders with a central resource for information about our efforts, including announcements, scientific papers, and new developments. Currently, the content is based on publicly available information, but we would like add the ACTIV leadership and working group members. Your representation on ACTIV demonstrates the breadth and depth of expertise and experience from all sectors committed to this effort. **Please send your responses to me, cc'ing Renate Myles, Abbey Meltzer and David Wholley by 12:00 p.m. ET tomorrow, Friday, May 15, if you agree to be listed as part of the ACTIV membership.**

Thanks,
 Francis

Francis Collins, MD, PhD
 NIH Director

From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 7/30/2020 11:33:41 AM
To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freirem]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]
Subject: RE: [EXTERNAL] Materials for July 29 ACTIV Executive Committee Teleconference

OK.

From: Adam, Stacey (FNIH) [T] <(b) (6)>
Sent: Wednesday, July 29, 2020 11:05 PM
To: Wholley, David (FNIH) [T] <(b) (6)> Lane, Cliff (NIH/NIAID) [E] <(b) (6)> Collins, Francis (NIH/OD) [E] <(b) (6)> Freire, Maria (FNIH) [T] <(b) (6)> Austin, Christopher (NIH/NCATS) [E] <(b) (6)> Tabak, Lawrence (NIH/OD) [E] <(b) (6)> Anderson, James (NIH/OD) [E] <(b) (6)> Parker, Ashley (NIH/OD) [E] <(b) (6)>
Subject: RE: [EXTERNAL] Materials for July 29 ACTIV Executive Committee Teleconference

Hi Team,

I just confirmed with the ACTIV-3 team they will be testing a subset of the patients from ACTIV-3, but it will be done under a separate protocol called INSIGHT 004 that is open at certain sites where the trial will be activated.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
Direct: (b) (6) | Mobile: (b) (6)

From: Wholley, David (FNIH) [T] (b) (6)
Sent: Wednesday, July 29, 2020 9:53 PM
To: Lane, Cliff (NIH/NIAID) [E] (b) (6) >; Collins, Francis (NIH/OD) [E] (b) (6) >; Freire, Maria (FNIH) [T] (b) (6) >; Austin, Christopher (NIH/NCATS) [E] (b) (6) >; Tabak, Lawrence (NIH/OD) [E] (b) (6) >; Anderson, James (NIH/OD) [E] (b) (6) >; Parker, Ashley (NIH/OD) [E] (b) (6)

Cc: Adam, Stacey (FNIH) [T] < (b) (6) >

Subject: RE: [EXTERNAL] Materials for July 29 ACTIV Executive Committee Teleconference

Stacey said there is collection of samples for genetic characterization in ACTIV-3. Copying her for clarification.

From: Lane, Cliff (NIH/NIAID) [E] (b) (6) >

Sent: Wednesday, July 29, 2020 6:20 PM

To: Wholley, David (FNIH) [T] (b) (6) >; Collins, Francis (NIH/OD) [E] (b) (6) >; Freire, Maria (FNIH) [T] (b) (6) >; Austin, Christopher (NIH/NCATS) [E] (b) (6) >; Tabak, Lawrence (NIH/OD) [E] < (b) (6) >; Anderson, James (NIH/OD) [E] (b) (6) >; Parker, Ashley (NIH/OD) [E] (b) (6)

Subject: Re: [EXTERNAL] Materials for July 29 ACTIV Executive Committee Teleconference

(b) (5)

(b) (5) I think it is something we could ask Team 2 to evaluate in the context of the treatment studies.

Cliff

From: "Wholley, David (FNIH) [T]" (b) (6)

Date: Wednesday, July 29, 2020 at 5:58 PM

To: "Collins, Francis (NIH/OD) [E]" < (b) (6) >, "Freire, Maria (FNIH) [T]" (b) (6) >, "Austin, Christopher (NIH/NCATS) [E]" (b) (6) >, "Lane, Cliff (NIH/NIAID) [E]" (b) (6) >, Lawrence Tabak < (b) (6) >, "Anderson, James (NIH/OD) [E]" < (b) (6) >, "Parker, Ashley (NIH/OD) [E]" < (b) (6) >

Subject: RE: [EXTERNAL] Materials for July 29 ACTIV Executive Committee Teleconference

Francis, I composed the following reply to Robert for your consideration. I'm happy to send it (he wrote to both of us) or you can; feel free to edit of course in either case. Cliff, please weigh in on how I have characterized the NIAID study you mentioned this morning. Thanks

Hi Robert:

(b) (5)

Regards,
David

From: Collins, Francis (NIH/OD) [E] (b) (6)

Sent: Wednesday, July 29, 2020 7:43 AM

To: Freire, Maria (FNIH) [T] < (b) (6) >; Wholley, David (FNIH) [T] (b) (6) >; Austin, Christopher (NIH/NCATS) [E] (b) (6) >; Lane, Cliff (NIH/NIAID) [E] < (b) (6) >; Tabak, Lawrence (NIH/OD) [E] < (b) (6) >; Anderson, James (NIH/OD) [E] < (b) (6) >; Parker, Ashley (NIH/OD) [E] < (b) (6) >

Subject: FW: [EXTERNAL] Materials for July 29 ACTIV Executive Committee Teleconference

From: Plenge, Robert <(b) (6)>
Sent: Wednesday, July 29, 2020 7:33 AM
To: Wholley, David (FNIH) [T] (b) (6); Collins, Francis (NIH/OD) [E] (b) (6)
Subject: Re: [EXTERNAL] Materials for July 29 ACTIV Executive Committee Teleconference

Given the recent genetic data ([here](#), [here](#), [here](#), [here](#)), is it worth considering more routine genetic testing (e.g., GWAS, WES) in ACTIV trials to guide future repurposing?

From: "Melencio, Cheryl (FNIH) [T]" (b) (6) > on behalf of "Wholley, David (FNIH) [T]" (b) (6)

Date: Tuesday, July 28, 2020 at 10:55 PM

To: "Austin, Christopher (NIH/NCATS) [E]" (b) (6) >, "Bancel, Stephane" (b) (6), "Carter, Kara" <(b) (6)>, "Cavaleri, Marco" (b) (6), "Cihlar, Tomas" <(b) (6)>, "Collins, Francis (NIH/OD) [E]" (b) (6) >, "Corey, Larry" <(b) (6)>, "Culp, Michelle (NIH/OD) [E]" <(b) (6)>, "Disbrow, Gary (OS/ASPR/BARDA)" (b) (6), "Dolsten, Mikael" <(b) (6)>, "Erbelding, Emily (NIH/NIAID) [E]" <(b) (6)>, "Erck, Stan" (b) (6), "Fauci, Anthony (NIH/NIAID) [E]" (b) (6), "Freire, Maria (FNIH) [T]" (b) (6) >, "Gadbois, Ellen (NIH/OD) [E]" (b) (6), "Gibbons, Gary (NIH/NHLBI) [E]" <(b) (6)>, "Hudson, Thomas" (b) (6) >, "James, Stephanie (FNIH) [T]" <(b) (6)>, "Johnson, Robert (OS/ASPR/BARDA)" <(b) (6)>, "Kramer, Lynn" <(b) (6)>, "Lane, Cliff (NIH/NIAID) [E]" (b) (6) >, "Lepore, John" (b) (6), "Marks, Peter (FDA/CBER)" <(b) (6)>, "Marston, Hilary (NIH/NIAID) [E]" (b) (6) >, "Mascola, John (NIH/VRC) [E]" (b) (6) >, "Meeker, David" <(b) (6)>, "Menetski, Joseph (FNIH) [T]" (b) (6), "Messonnier, Nancy (CDC/DDID/NCIRD/OD)" (b) (6) >, "Pandya, Hitesh" <(b) (6)>, "Pangalos, Mene" (b) (6) >, "Pao, William" (b) (6) >, "Parker, Ashley (NIH/OD) [E]" (b) (6) >, "Paul, Steve" <(b) (6)>, "Perlmutter, Roger" <(b) (6)>, "Plenge, Robert" (b) (6), "Plump, Andy" <(b) (6)>, Rachel Ramoni (b) (6) >, "Rasi, Guido" <guido.rasi@ema.europa.eu>, "Reed, John" <(b) (6)>, "Reese, David" <(b) (6)>, "Rouse, Doris" <(b) (6)>, "Santos, Michael (FNIH) [T]" (b) (6), "Skovronsky, Daniel" (b) (6), "Stein, Peter (FDA/CDER)" <(b) (6)>, "Stoffels, Paul" (b) (6), "Tabak, Lawrence (NIH/OD) [E]" (b) (6), "Talley, Michael" (b) (6) >, "Tsai, John" (b) (6), "Vessey, Rupert" (b) (6), "Virgin, Skip" (b) (6), "Wholley, David (FNIH) [T]" (b) (6) >, "Woodcock, Janet (FDA/CDER)" (b) (6) >, "Young, John" <(b) (6)>, "Colvis, Christine (NIH/NCATS) [E]" (b) (6), "Desrosiers, Betsy" (b) (6), Eric Hughes (b) (6) >, "Jansen, Kathrin" (b) (6), "Kurilla, Michael (NIH/NCATS) [E]" <(b) (6)>, "Lowy, Douglas (NCI)" <(b) (6)>, "Read, Sarah (NIH/NIAID) [E]" <(b) (6)>, "Young, John" <(b) (6)>
Cc: "Bianchi, Diana (NIH/NICHD) [E]" (b) (6), "Byrnes, Noni (NIH/CSR) [E]" <(b) (6)>, "Glass, Roger (NIH/FIC) [E]" <(b) (6)>, "Hodes, Richard (NIH/NIA) [E]" <(b) (6)>, "Koob, George (NIH/NIAAA) [E]" <(b) (6)>, "Koroshetz, Walter (NIH/NINDS) [E]" <(b) (6)>, "Langevin, Helene (NIH/NCCIH) [E]"

< (b) (6) "Norris, Andrea (NIH/CIT) [E]" < (b) (6) "Perez-Stable, Eliseo (NIH/NIMHD) [E]" (b) (6) >, "Rodgers, Griffin (NIH/NIDDK) [E]" < (b) (6) "Schwetz, Tara (NIH/OD) [E]" < (b) (6) "Sharpless, Norman (NIH/NCI) [E]" < (b) (6) "Tucci, Debara (NIH/NIDCD) [E]" (b) (6) >, "Tumminia, Santa (NIH/NEI) [E]" (b) (6) >, "Volkow, Nora (NIH/NIDA) [E]" (b) (6) "Woychik, Rick (NIH/NIEHS) [E]" < (b) (6) "Adam, Stacey (FNIH) [T]" < (b) (6) "Alvarez, Rosa" < (b) (6) "Anderson, Margaret" < (b) (6) "Chen, Helen" < (b) (6) "Elsaid, Olivia" (b) (6) "Gonzalez, Nina" < (b) (6) "James, Stephanie (FNIH) [T]" (b) (6) "Menetski, Joseph (FNIH) [T]" (b) (6) >, "Santos, Michael (FNIH) [T]" < (b) (6) "Stratton, Ben" (b) (6) >, "Tolman, Brett" < (b) (6) "Tountas, Karen (FNIH) [T]" (b) (6) >, "Wachtel, Jonathan" < (b) (6) >, "Wholley, David (FNIH) [T]" (b) (6) >, "Anderson, James (NIH/OD) [E]" (b) (6) "Burklow, John (NIH/OD) [E]" (b) (6) >, "Castillejos, Carlos" (b) (6) >, "Culp, Michelle (NIH/OD) [E]" (b) (6) FNIH Central Account < (b) (6) "Freire, Maria (FNIH) [T]" (b) (6) "Gadbois, Ellen (NIH/OD) [E]" (b) (6) "Wolinetz, Carrie (NIH/OD) [E]" < (b) (6) >, "Burklow, John (NIH/OD) [E]" < (b) (6) "Gorman, Greta (FNIH) [T]" < (b) (6) "Hallett, Adrienne (NIH/OD) [E]" (b) (6) >, "Meltzer, Abbey (FNIH) [T]" (b) (6) "Myles, Renate (NIH/OD) [E]" < (b) (6) "Melencio, Cheryl (FNIH) [T]" < (b) (6)

Subject: [EXTERNAL] Materials for July 29 ACTIV Executive Committee Teleconference

Resent-From: (b) (6) >

[Use CAUTION when opening links/attachments]

Dear ACTIV EC members, Working Group Co-Chairs, and meeting participants:

Please see attached the PowerPoint slides, including the agenda, for our meeting (via Zoom) from 2:30 PM to 4:00 PM Eastern U.S. time tomorrow, Wednesday July 29. I have also attached notes from our July 1 Leadership Team meeting as well as our last ACTIV EC meeting on July 15.

The Zoom meeting information is:

Join Zoom Meeting

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Password: 150160

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Please let Joe Menetski or Cheryl Melencio here at FNIH (copied) know if you are having any problems connecting. I look forward to a productive meeting.

Regards,

David

David Wholley
Senior Vice-President, Research Partnerships
Foundation for the National Institutes of Health

(b) (6)

fnih.org

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In 2019, the FNIH earned the highest rating from Charity Navigator for the fifth consecutive year and was recognized as an organization that exceeds industry standards.

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 11/10/2020 7:59:58 PM
To: Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Draghia-Akli, Ruxandra [(b) (6) Eisner, Mark [(b) (6) Gottesdiener, Keith (b) (6) Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Kim, Elizabeth [(b) (6) LaVange, Lisa [(b) (6) Levy, Elliot [(b) (6) Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Menon, Sandeep [(b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Patel, Naimish (b) (6) Peppercorn, Amanda [(b) (6) Poole, Mike [(b) (6) Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Collins, Sylvia (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylvia.Colli]; Amanda Peppercorn [(b) (6) Garner, Carl (b) (6) Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Timothy Burgess [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=52e5e03dcbc847709eaab64457efa57e-TimothyBurg]; Reineck, Lora (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a62d88ba0c3b44e3bb922236c61304b3-reineckla]; Aggarwal, Neil (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c9de6615504ff9889f3b0c44a63526-aggarwalnr]; Rosenberg, Yves (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a5cb3e9a3a2747c38c42f68f5c8e40cf-rosenbey]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Brown, Jeremy (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce971eefec944a68a94add3b24835f5-brownj7]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Jacqueline Kirchner [(b) (6) Beigel, John (NIH) [E] [/o=ExchangeLabs/ou=Exchange Administrative

Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=492ae062f7d74e3cbd894e30160869f0-jbeigel]; Phillips, L Revell CIV DTRA RD (USA) [(b) (6) Petrovick, Martha - 0449 - MITLL [(b) (6) (b) (6) Sizemore, Christine (NIH/FIC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=05494833e0fc47a9acac194cd338b201-csizemore]

CC: Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy [(b) (6) Jansen, Kathrin [(b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Young, John (b) (6) Biggs, Mary [(b) (6) Butcher, Tina [(b) (6) Demarcus [(b) (6) Macone, Erin [(b) (6) Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Salathin, Carla [(b) (6) Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Wachtel, Jonathan (b) (6) btolman [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user7b137a1e]; Alvarez, Rosa Maria [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user706e5647]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Dana Carluccio [(b) (6) Rose Li Central Account [(b) (6) Margaret Anderson [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab9a138f1e284c689fedfb10b8cc5295-marganderso]; Lucas Smalldon [Lucas.Smalldon@roseliassociates.com]; Stratton, Benjamin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=usere3ed7188]; (b) (6) Mollica, Linda /US [(b) (6) Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Marston, Hilary (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab30660917b942ffba9ae95d631116f3-marstonhd]; Chen, Helen Q. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user34aa917e]; Wung, Peter /US [(b) (6) Hoots, W. Keith (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=328221d5416d4fc59262c6c2eca59d4c-hootswk]; Groesch, Mary (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=69ab77a4c9bf499383186b9d9870344e-groeschm]; Shipp, Allan (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=16001e8ab49c4489aef107bd0ce27715-shippa]; Kindzelski, Andrei (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8bda5194bdca4d2594626f6313d2db5c-kindzelskia]; Hone, David M (Dave) CIV DTRA J9 (USA) [(b) (6) Reisler, Ronald B CTR USARMY DOD JPEO CBRND (USA) [(b) (6) Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Elsaid, Olivia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userf0efa7bd]; Walker, Paula (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fbe81b9b832e40acb5fd03b3cf32930-walkerp1]; Bethany Stokes [(b) (6) asorosa [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userffc6da86]

Subject: Potential Digital Symposium of Interest to ACTIV TX-Clinical WG

Dear ACTIV TX-Clinical WG Members,

Some of our NIH colleagues felt that you all might be interested in the meeting below. There will be a number of talks that will discuss post-pandemic clinical trial planning and modifications based on lessons that we have learned.

Looking forward to seeing you all Thursday!

Kind regards,
Stacey

The 17th Global CardioVascular Clinical Trialists (CVCT) Forum from December 3-December 7th, 2020, will be virtual, and we would like to offer this as an opportunity for all NIH clinical trialists to participate and benefit from free registration this year. We hope that you, as an NIH clinical trialist, will appreciate the opportunity to experience the CVCT uniqueness, if you haven't participated in past meetings. Registration will allow you to attend all 45 sessions, listen to over 300 presentations and network and debate virtually with over 250 key trialists LIVE.

CVCT is a unique think tank forum dedicated to clinical trial science in the space of CardioVascular, CardioRenal and Cardiometabolic diseases. It is also the place where critical latest trials, are discussed in depth, individually and in context. Discussion includes understanding trial rationale, design issues, trial conduct and operational issues, statistical methodology and interpretation, clinical meaning, approvability by major regulatory agencies, valuation by payers and implementation in clinical practice.

CVCT assembles the key highest level global experts from multiple backgrounds, including Academy, Regulatory agencies (FDA,EMA, MHRA, etc...), Industry, CROs, Major journal editors(NEJM, The Lancet, JAMA, Circ, JACC, EHJ.), Major research organisations (NIH, EU, Inserm..), Payers (CMS, NICE, HTA organisations), Lawyers and Patients.

Learn more about the CVCT Forum you can visit the website: <https://www.globalcvctforum.com/>

We look forward to your active participation at Digital CVCT2020.

REGISTER FOR FREE

<https://www.globalcvctforum.com/registration-2020>

Faiez Zannad

Emeritus Professor of Therapeutics and Cardiology Inserm and Université de Lorraine, CHU Nancy, France Founder and Chairman. 17th Global CardioVascular Clinical Trialists Forum December 3 - 7, 2020, Washington D.C.

Stacey J. Adam, PhD

Director, Cancer

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From: Tountas, Karen (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=40C04FEF6F1E46F5B750753CD5A14F93-TOUNTASKH]
Sent: 4/27/2020 6:54:39 PM
To: Bascles, Lionel [(b) (6)] Cohen, Myron [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2141b9e28c1a421fb3c1c4f75dd4c457-myron_cohen]; Corey, Larry [(b) (6)] Victoria Davey [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c8291f38ec342f895243c0617e115ec-victoria.da]; Desrosiers, Betsy [(b) (6)] Dickens, Jim (NIH/NCATS) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12591c90404e46caba73079cf4a5e2ea-dickensj]; Doroshow, James (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a1d0fb9f055940c39b387cae2485faa6-doroshoj]; Garner, Carlos [(b) (6)] Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Nayak, Seema (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=51d5ee6848004578b5bf9c808eca8f6f-nayaksu]; Payton, Manizhe (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=81d1c1824bfa438a94da81520a8bca90-paytonma]; Resnansky, Laura [(b) (6)] Sizemore, Christine (NIH/FIC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=05494833e0fc47a9acac194cd338b201-csizemore]; Srinivasan, Badhri [(b) (6)] Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Vincent, Mike [(b) (6)] Wachtel, Jonathan [(b) (6)]; Woodcock, Janet (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebfcf48879f92169bd7644e29-Janet.Woodc]
CC: Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hughes, Eric [(b) (6)] Jansen, Kathrin [(b) (6)] Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Young, John [(b) (6)] Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; Anderson, Margaret [(b) (6)] Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Carluccio, Dana [(b) (6)] Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Heaton, Penny [(b) (6)] James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Li, Rose [(b) (6)] Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Tuveson, Nancy [(b) (6)] Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Criffield, Robin [(b) (6)] Hamilton, Nancy [(b) (6)] Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Minnich, Beth [(b) (6)]; Mueller-Reichenstein, Petra [petra. (b) (6)] Quadros, Nora [(b) (6)] Katz, Rebecca (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8e2b174d9bf748e9aa5ed901b4c5a3d9-katzrd]; Thomas, Ashley (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=1bcd5d3f7c1e4309a251d013e1cc89b0-Ashley.Thom]; Hill, Zoe (NIH/NHLBI)
[C] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=a19ee51dca2a443d883a15e025d6e1e0-hillzs]

Subject: Clinical Trial Capacity Working Group Meeting #4 Summary

Attachments: Clinical_Trial_Capacity_Working_Group_Meeting #4_Summary_Draft-FINAL.pdf

Dear Clinical Trial Capacity WG Members,

Attached is the summary for the full working group meeting that took place last week (Friday, April 24). The next WG meeting is scheduled for tomorrow, Tuesday, April 28 at 9am EST.

With best regards,
Karen

Karen H. Tountas, PhD
Scientific Program Manager
Foundation for the National Institutes of Health

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Sent: 8/26/2020 12:26:16 PM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
CC: Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]
Subject: FW: Next Vaccines Working Group meeting: Friday, 14 Aug

This was the 8/14 meeting but I do not have any notes yet. The AZ Brazil trial did come up on the call and Kathrin raised the issue of a trial receiving approval in another country and asked how would this affect trials in the US – defer to Mike for details.

From: Santos, Michael (FNIH) [T] < (b) (6) >
Sent: Friday, August 7, 2020 12:49 PM
To: (b) (6) Lowy, Douglas (NIH/NCI) [E] < (b) (6) > (b) (6)
Arvin, Ann < (b) (6) > Beth Bell < (b) (6) > < (b) (6) > (b) (6)
Cavaleri Marco < (b) (6) > (b) (6) (b) (6)
(b) (6) Greg Glenn < (b) (6) > (b) (6) Haynes, Barton
< (b) (6) > (b) (6) (b) (6) Marks, Peter (FDA/CBER)
< (b) (6) > Mascola, John (NIH/VRC) [E] < (b) (6) > Messonnier, Nancy
(CDC/DDID/NCIRD/OD) < (b) (6) > Nelson Michael < (b) (6) > Offit, Paul
< (b) (6) > (b) (6) Seals, Jonathan (OS/ASPR/BARDA) < (b) (6) >
(b) (6) (b) (6) Tal Zaks < (b) (6) >
Cc: Tolman, Brett < (b) (6) > (b) (6) Hopps, Markay < (b) (6) >
Kozlowski, Mary (NIH/NCI) [C] < (b) (6) > Johnson, Maureen (NIH/NCI) [E]
< (b) (6) > (b) (6) Jeneffer Haynes < (b) (6) >
(b) (6) (b) (6) (b) (6) Austin, Sarah (NIH/NIAID) [E]
< (b) (6) > (b) (6) Isabel Ramsey < (b) (6) > Parker,
Ashley (NIH/OD) [E] < (b) (6) > Marston, Hilary (NIH/NIAID) [E] < (b) (6) > Qashu, Felicia
(NIH/OD) [E] < (b) (6) > Culp, Michelle (NIH/OD) [E] < (b) (6) > Gadbois, Ellen (NIH/OD) [E]
< (b) (6) > Wholley, David (FNIH) [T] < (b) (6) > Melencio, Cheryl (FNIH) [T]
< (b) (6) > Menetski, Joseph (FNIH) [T] < (b) (6) > Adam, Stacey (FNIH) [T] < (b) (6) >
Tountas, Karen (FNIH) [T] < (b) (6) > James, Stephanie (FNIH) [T] < (b) (6) > Colvis, Christine
(NIH/NCATS) [E] < (b) (6) > Desrosiers, Betsy < (b) (6) > Eric Hughes
< (b) (6) > Kurilla, Michael (NIH/NCATS) [E] < (b) (6) > Read, Sarah (NIH/NIAID) [E]
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Roman < (b) (6) > Hamilton, Holli (OS/ASPR/BARDA) < (b) (6) > Modjarrad, Kayvon
CIV USARMY MEDCOM WRAIR (USA) < (b) (6) > Kathleen Neuzil
< (b) (6) > Schrag, Stephanie (CDC/DDID/NCIRD/DBD) < (b) (6) > Verani, Jennifer R.
(CDC/DDID/NCIRD/DBD) < (b) (6) > Thornburg, Natalie (CDC/DDID/NCIRD/DVD) < (b) (6) > Gonzalez,
Nina < (b) (6) > 'Wachtel, Jonathan' < (b) (6) > Stratton, Benjamin
< (b) (6) > Anderson, Margaret < (b) (6) > (b) (6)
(b) (6) Bethany Stokes < (b) (6) > Kathleen Callahan
< (b) (6) > Molloy, Delia (DPH) < (b) (6) > Jacqueline Miller
< (b) (6) > Kayvon Modjarrad < (b) (6) >
Subject: Next Vaccines Working Group meeting: Friday, 14 Aug

Dear Vaccines Working Group members,

The next meeting of the Working Group will be next Friday, 14 Aug, at 1:30pm ET (10:30am PT / 7:30pm CEST). A calendar invite follows.

APAR0000010211-2515764

The agenda topic is the possibility of perceived or actual political pressure to introduce a vaccine prior to evaluation of the vaccine against the stated success criteria (or perhaps despite an apparent failure to meet those criteria), and the implications of this possibility for public confidence in vaccines.

Relevant to this topic: At today's meeting of the Vaccines Clinical Trials Sub-Group, our discussion of the potential implications of the first vaccine success included a discussion of EUA in the US. Our members from the FDA shared emphatically that an EUA decision on the first successful vaccine will require clinical efficacy data, in addition to safety and CMC data. (Subsequent evaluation of other vaccine candidates could in principle proceed through various pathways.)

We're looking forward to our meeting. Please feel free to reach out with any questions or suggestions.

Best regards,
Brett and Mike

Michael Santos, PhD
Associate Vice President, Science | Foundation for the National Institutes of Health

From: Santos, Michael (FNIH) [T]
Sent: Sunday, August 2, 2020 11:01 AM
Subject: Notes from the Vaccines Working Group meeting

Dear Vaccines Working Group members,

As described in the agenda email (below), we discussed the evolution of the Vaccines Working Group at our last meeting. Please see the attached notes for a summary of the topics proposed as ongoing and future priorities for the group.

In addition, please note that the current plans for future meetings within the Working Group are:

- Vaccines Working Group: to meet as needed, determined by Kathrin and Doug (and potentially at the request of ACTIV Leadership).
- Vaccines Clinical Trials Sub-Group: to meet every other week.
- Other Sub-Groups: Not planning to meet beyond completing existing priorities, such as the vaccine-associated enhanced disease article and summary.

And one related update since the meeting: the vaccine-associated enhanced disease manuscript has been submitted; our gratitude to this group for your input, and our congratulations to the authors and especially Ann and Bart for leading this impressive contribution to this milestone.

Please reach out with any questions or suggestions.

Best regards,
Brett and Mike

Michael Santos, PhD
Associate Vice President, Science | Foundation for the National Institutes of Health

From: Santos, Michael (FNIH) [T]
Sent: Tuesday, July 28, 2020 2:58 PM
Subject: Agenda for tomorrow's (Wednesday's) Vaccines Working Group meeting

Dear Vaccines Working Group members,

We're looking forward to our next meeting, tomorrow (Wednesday) at 10am ET / 7am PT / 4pm CEST.

This week is the 16th of the Vaccines Working Group, and Francis Collins will join the start of tomorrow's meeting to recognize the progress we have made. Additionally, we have been asked by ACTIV leadership to consider how the Working Group should operate from here.

We are deeply grateful to all of you for your engagement in our collective efforts. We have identified and addressed many important topics for COVID-19 vaccine development and we have additional contributions yet to come, such as the article on vaccine-associated enhanced disease.

At this meeting we would like to discuss the topics that the group would prioritize going forward. We want to support the Working Group to continue to take on issues where we have unique value to add while adjusting the number and frequency of meetings to ensure we are being efficient with everyone's time.

Please come to the meeting with your perspective on what topics are important for the Working Group to address; in the immediate term we plan to continue conversations about the implications of the first vaccine success and of course continue with the dissemination of the vaccine-associated enhanced disease findings. **If you are unable to attend the meeting, as always your thoughts are welcome via email.**

Finally, we want to acknowledge and apologize for the overlap of tomorrow's meeting with the start of the [ACIP meeting](#). We know some of you are directly involved with ACIP and will miss the Working Group meeting. Certainly we will wrap up as soon as our discussion is finished for those who would like to hop over to the ACIP meeting afterwards.

Best regards,
Brett and Mike

Michael Santos, PhD
Associate Vice President, Science | Foundation for the National Institutes of Health

From: Santos, Michael (FNIH) [T]
Sent: Saturday, July 25, 2020 5:01 PM
Subject: Notes from the Vaccines Working Group meeting

Dear Vaccines Working Group members,

Thank you for your participation in the meeting. The meeting notes and materials are attached.

We're also grateful for the feedback you have provided on the vaccine-associated enhanced disease manuscript. Ann and Bart are working through that now, and we look forward to submitting the final version soon.

We will be in touch again soon about this week's meeting (Wednesday, 10am ET), and in the meantime please feel free to reach out with any questions or suggestions.

Best regards,
Brett and Mike

Michael Santos, PhD
Associate Vice President, Science | Foundation for the National Institutes of Health

From: Santos, Michael (FNIH) [T]
Sent: Tuesday, July 21, 2020 10:05 PM
Subject: Agenda for the Vaccines Working Group meeting

Dear Vaccines Working Group members,

We're looking forward to our meeting tomorrow (Wednesday), at 1:30pm ET (10:30am PT / 7:30pm CEST).

The agenda topics are:

- Brief update on the vaccine-associated enhanced disease manuscript
 - As a reminder, this is a product of the Working Group and all Working Group members are invited to provide feedback by Thursday at 8pm ET (see attached email sent by Brett on Monday)
- Follow-up discussion of approaches for non-specific immunity
 - Doug will lead this discussion. If you missed the discussion at last week's meeting, the notes are attached again.

As always, please let us know if you have any questions or input.

Best regards,
Brett and Mike

Michael Santos, PhD
Associate Vice President, Science | Foundation for the National Institutes of Health

From: Santos, Michael (FNIH) [T]
Sent: Sunday, July 19, 2020 4:04 PM
Subject: Notes from the Vaccines Working Group meeting

Dear Vaccines Working Group members,

Thank you for your participation in our last meeting, and particular thanks to Bob Gallo and Konstantin Chumakov and Paula for their presentations and discussion. Attached are the notes and slides presented.

As always, please don't hesitate to reach out with any comments or questions.

Best regards,
Brett and Mike

Michael Santos, PhD
Associate Vice President, Science | Foundation for the National Institutes of Health

From: Santos, Michael (FNIH) [T]
Sent: Friday, July 10, 2020 11:28 PM
Subject: Agenda for the Vaccines Working Group meeting Monday

Dear Vaccines Working Group members,

We're looking forward to our next meeting, Monday at 12pm ET (9am PT / 6pm CEST). There are two agenda topics for the meeting:

- The potential for OPV to provide temporary protection against COVID-19
 - Bob Gallo and colleagues will join to discuss their concept with the group
- A recap of the discussion Thursday in the Vaccines Clinical Trials Sub-Group meeting on the implications of the first vaccine licensure on other vaccine efficacy trials

As inputs to those conversations, the notes from the Clinical Trials Sub-Group meeting are attached along with two press articles and a compendium of journal articles about the OPV concept.

Please don't hesitate to reach out with any questions or feedback.

Best regards,
Brett and Mike

Michael Santos, PhD
Associate Vice President, Science
Foundation for the National Institutes of Health

(b) (6) | fnihi.org
11400 Rockville Pike, Suite 600, North Bethesda, MD 20852



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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 4/20/2020 12:04:05 AM
To: Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Draghia-Akli, Ruxandra [(b) (6)]; Eisner, Mark [(b) (6)]; Gottesdiener, Keith [(b) (6)]; Hughes, Eric [(b) (6)]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Kim, Elizabeth [(b) (6)]; LaVange, Lisa [(b) (6)]; Levy, Elliot [(b) (6)]; Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Menon, Sandeep [(b) (6)]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Patel, Naimish [(b) (6)]; Peppercorn, Amanda [(b) (6)]; Poole, Mike [(b) (6)]; Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Collins, Sylvia (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylva.Coli]; Amanda Peppercorn [(b) (6)]
CC: Butcher, Tina [(b) (6)]; Demarcus [(b) (6)]; Macone, Erin [(b) (6)]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Salathin, Carla [(b) (6)]; Mary Biggs [(b) (6)]
Subject: ACTIV Therapeutics-Clinical Working Group - Meeting Scheduling for the Week of Apr 27-May1

Dear ACTIV Therapeutics-Clinical WG Members,

I hope you all have had a great weekend! While we have a solid agenda planned for this week, we are already looking ahead to ensure we have the time we need on your calendars for following week. With this in mind we were wondering if we could keep the same cadence of meetings next week for the main group and the subgroup that we have this week, or if we need repoll. If we keep the same cadence the meetings would on the follow days.

Monday April 27th

- o Therapeutics Clinical Master Protocol Subgroup Meeting #5 (2:00PM – 3:00PM US EST)

Tuesday April 28th

- o Therapeutics Clinical Master Protocol Subgroup Meeting #6 (1:00PM – 2:00PM US EST)
- o Therapeutics Clinical Agent Prioritization Subgroup Meeting #4 (2:00PM – 3:00PM US EST)

Wednesday April 29th

- o Therapeutics Clinical Agent Prioritization Subgroup Meeting #5 (2:00PM – 3:00PM US EST)

Thursday April 30th

- o Therapeutics Clinical Work Group Meeting #4 (2:00PM – 3:00PM US EST)

Friday May 1st

Please let us know as soon as you can if these times can be held for standing meetings, understanding that we may need a few adhoc meetings, as well.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
Foundation for the National Institutes of Health
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fnih.org
11400 Rockville Pike, Suite 600, North Bethesda, MD 20852



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From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 4/13/2020 8:19:23 PM
To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]
Subject: RE: Follow-up from 1st Meeting of COVID PPP Therapeutics-Clinical Working Group - RAPID RESPONSE REQUESTED

Hi Stacey,

It's nice to meet you via email! Please keep me on both groups as I will be tracking items for Dr. Collins. I remain flexible regarding the time windows and defer to what works best for the WG members.

Thanks,
Ashley

Ashley Parker, Ph.D.
Special Assistant to Acting Chief of Staff to the NIH Director
Office of the Director | National Institutes of Health
Tel: (b) (6)



From: Adam, Stacey (FNIH) [T] <(b) (6)>
Sent: Monday, April 13, 2020 3:23 PM
To: Bozzette, Sam (NIH/NCATS) [E] <(b) (6)> Butterton, Joan <(b) (6)> De Claro, R. Angelo (FDA/CDER) <(b) (6)> Draghia-Akli, Ruxandra <(b) (6)> Eisner, Mark <(b) (6)> Gottesdiener, Keith <(b) (6)> Hughes, Eric <(b) (6)> Judy Currier <(b) (6)> Kim, Elizabeth <(b) (6)> LaVange, Lisa <(b) (6)> Levy, Elliot <(b) (6)> Mellors, John W <(b) (6)> Menon, Sandeep <(b) (6)> Parker, Ashley (NIH/OD) [E] <(b) (6)> Patel, Naimish <(b) (6)> Peppercorn, Amanda <(b) (6)> Poole, Mike <(b) (6)> Proschan, Michael (NIH/NIAID) [E] <(b) (6)> Read, Sarah (NIH/NIAID) [E] <(b) (6)> Santos, Michael (FNIH) [T] <(b) (6)> Shen, Yuan Li (FDA/CDER) <(b) (6)> Stein, Peter (FDA/CDER) <(b) (6)> Collins, Francis (NIH/OD) [E] <(b) (6)> Wholley, David (FNIH) [T] <(b) (6)>
Cc: Colvis, Christine (NIH/NCATS) [E] <(b) (6)> Desrosiers, Betsy <(b) (6)> Jansen, Kathrin <(b) (6)> Kurilla, Michael (NIH/NCATS) [E] <(b) (6)> Lowy, Douglas (NCI) <(b) (6)> Young, John <(b) (6)> Wood, Gretchen (NIH/OD) [E] <(b) (6)> Biggs, Mary <(b) (6)> Butcher, Tina <(b) (6)> Demarcus <(b) (6)> Macone, Erin <(b) (6)> Melencio, Cheryl (FNIH) [T] <(b) (6)> Salathin, Carla <(b) (6)> Tountas, Karen (FNIH) [T] <(b) (6)> Menetski, Joseph (FNIH) [T] <(b) (6)> James, Stephanie (FNIH) [T] <(b) (6)> Kim, Elizabeth <(b) (6)> Wachtel, Jonathan <(b) (6)> Tolman, Brett <(b) (6)> Alvarez, Rosa <(b) (6)> Gonzalez, Nina <(b) (6)>
Subject: Follow-up from 1st Meeting of COVID PPP Therapeutics-Clinical Working Group - RAPID RESPONSE REQUESTED
Importance: High

Dear ACTIV Therapeutics-Clinical WG,

Thank you all for a very productive discussion today. We appreciate all of you taking the time to join the meeting.

As discussed on the call today, I am reaching out to ask for volunteers for each of the two main sub-groups for our WG:

1. Agent Prioritization Process, Criteria, and Initial Agent List
2. Development of COVID Master Protocols

Please send me your availability to participate and your preference for which sub-group you would like to join. In addition, please send your preferred time windows or any restricted times over the next two days. Please send me this information by no later than 10 pm US ET today if you can. This will allow us to plan the meetings rapidly for Tuesday and Wednesday.

We will be working to get together agendas and will share them as they come together.

In addition to sending the information above, Tim Buchman from BARDA asked me to share the attached materials and the thoughts below for consideration on our use of the ARDS terminology.

A Remark on Terminology: "ARDS" as an expression of COVID-19

Contemporary respiratory distress syndromes were unknown until the 1960s. Prior to the invention and diffusion of mechanical ventilators following the polio epidemics of the 1950s, patients simply succumbed to severe pneumonia.

In 1967, David Ashbaugh, Tom Petty and others reported a case series of a dozen patients who experienced severe respiratory illness with chest radiographs similar to what would be observed in congestive heart failure but without the heart failure (pdf attached). The lungs simply leaked fluid.

The history of that report is summarized by Levine (one of the authors of the 1967 report) and is also attached.

Pertinent to the next half century of ARDS are the following:

- (a) "ARDS" was recognized as a final common pathway to diverse insults including (but not limited to) trauma, pancreatitis, pneumonia, and anatomically distant sepsis;*
- (b) development of a standard supportive strategy namely "lung protective, low-tidal volume ventilation" that emerged from ARDSNET (see <https://www.nejm.org/doi/full/10.1056/NEJM200005043421801>) but in fact simply reflected normal tidal volumes across all mammals, see figure 1 in the Tenney and Remmers 1963 paper, pdf attached.*
- (c) a contemporary definition of ARDS that focuses almost exclusively on the extent of hypoxemia without attention to the defect in diffusion of oxygen across the alveolar-capillary membrane (the Berlin criteria, pdf attached).*

Thus until 2020, ARDS accumulated underlying pathogeneses. As a consequence, treatment focused on "greatest good for greatest number". Whilst address of the underlying cause has always been part of ARDS treatment, the ventilator support regimen has been largely "one size fits most".

SARS-CoV-2 has changed the landscape. A single pathogen has affected populations of diverse heritable and acquired underlying pulmonary conditions. The pathophysiologic responses to the pathogen are partitioning into several endotypes. This has prompted both experts and pundits to call for a revision of the "one size fits most" into more tailored approaches. See the Gattinoni pdf published a couple of weeks ago in the ATS journal (pdf attached.)

There is a manuscript from John Marini and Gattinoni that will run in one of the journals I edit in the near future focusing on how ventilators injure vulnerable lungs. Luciano Gattinoni has separately contacted one of my Associate Editors to write a piece for the other journal that I edit. Suffice it to say that the conversation about partitioning treatment into approaches that reflect the expression of COVID-19 could well be part of the presentation.

I share all of the above information simply to highlight the fact that convolving the pulmonary injury consequent to SARS-CoV-2 with the term "ARDS" brings a half-century of knowledge—and also of baggage—to the therapeutics conversation. Perhaps we should be as careful and specific in the terms we choose to describe the pulmonary injury as we should be in testing candidate therapies.

Our choice of words, like our choice of drugs, matters.

Tim

Timothy G. Buchman, PhD, MD

Senior Advisor

IPA to the DRiVe (Division of Research, Innovation and Ventures)

Biomedical Advanced Research and Development Authority (BARDA)

Office of Assistant Secretary for Preparedness and Response (ASPR)

U.S. Department of Health and Human Services (HHS)

Thank you all in advance for your timely responses.

Thanks,

Stacey

Stacey J. Adam, PhD

Director, Cancer

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From: Myles, Renate (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7D317F5626934585B3692A1823C1B522-MYLESR]
Sent: 5/18/2020 1:37:20 PM
To: Wooldridge, Shannon (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=385b0c281f104789873e956dc91b7c06-burdense]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Pollock, Rachel (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4887cb3513e242dfa7d2df712dcc6d6a-pollockrc]
Subject: RE: Time sensitive: Making your ACTIV Participation Public

Thank you!

From: Wooldridge, Shannon (NIH/OD) [E] <(b) (6)>
Sent: Monday, May 18, 2020 9:17 AM
To: Myles, Renate (NIH/OD) [E] <(b) (6)> Parker, Ashley (NIH/OD) [E] <(b) (6)> Pollock, Rachel (NIH/OD) [E] <(b) (6)>
Subject: RE: Time sensitive: Making your ACTIV Participation Public

No replies from Baric, Deming, or Jansen in FC's inbox. I just ran a search.

From: Myles, Renate (NIH/OD) [E] (b) (6)
Sent: Monday, May 18, 2020 9:16 AM
To: Parker, Ashley (NIH/OD) [E] <(b) (6)> Pollock, Rachel (NIH/OD) [E] (b) (6)
Wooldridge, Shannon (NIH/OD) [E] (b) (6) <>
Subject: RE: Time sensitive: Making your ACTIV Participation Public
Importance: High

Hi Rachel and Shannon:

Would you check FC's mailbox for this information ASAP? We need to launch the webpage this morning.

Thanks,
Renate

From: Parker, Ashley (NIH/OD) [E] (b) (6) >
Sent: Monday, May 18, 2020 7:57 AM
To: Myles, Renate (NIH/OD) [E] (b) (6) >; Pollock, Rachel (NIH/OD) [E] (b) (6)
Wooldridge, Shannon (NIH/OD) [E] <(b) (6)>
Subject: Re: Time sensitive: Making your ACTIV Participation Public

Hi Renate, Rachel, and Shannon,

We've made lots of progress! Shannon — can we see if the 3 ACTIV participants responded to Dr. Collins privately over the weekend?

Thank you,
Ashley

On May 17, 2020, at 11:15 PM, Myles, Renate (NIH/OD) [E] (b) (6) > wrote:

Hi Ashley and Rachel:

Below are the three people I did not hear from. I searched my inbox. Just wanted to double check that they didn't just respond to Francis. Thanks, Renate

Ralph Baric, Ph.D.

William R. Kenan, Jr., Distinguished Professor, Department of Epidemiology
Professor, Department of Microbiology and Immunology
University of North Carolina, Gillings School of Global Public Health

(b) (6)

Damon Deming, Ph.D.

Virologist, Division of Antiviral Products, Office of New Drugs
U.S. Food and Drug Administration

(b) (6)

Kathrin Jansen, Ph.D.

Senior Vice President and Head of Vaccine Research and Development
Pfizer

(b) (6)

From: Collins, Francis (NIH/OD) [E] <(b) (6)>

Sent: Thursday, May 14, 2020 11:00 AM

To: Collins, Francis (NIH/OD) [E] (b) (6)

Cc: Myles, Renate (NIH/OD) [E] <(b) (6)>; Meltzer, Abbey (FNIH) [T] <(b) (6)>

Wholley, David (FNIH) [T] <(b) (6)>

Subject: Time sensitive: Making your ACTIV Participation Public

Dear ACTIV Colleagues:

Yes, this message is for you, though your address was in the bcc line!

NIH would like to launch an ACTIV webpage to provide stakeholders with a central resource for information about our efforts, including announcements, scientific papers, and new developments. Currently, the content is based on publicly available information, but we would like add the ACTIV leadership and working group members. Your representation on ACTIV demonstrates the breadth and depth of expertise and experience from all sectors committed to this effort. **Please send your responses to me, cc'ing Renate Myles, Abbey Meltzer, and David Wholley by 12:00 p.m. ET tomorrow, Friday, May 15, if you agree to be listed on the web site as part of the ACTIV team.**

Thanks,
Francis

Francis S. Collins, MD, PhD
NIH Director

From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 5/1/2020 12:10:14 PM
To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; Eric Hughes [(b) (6)]; Read, Sarah (NIH/NIAID) [E] [(b) (6) .gov]; Ruxandra Draghia-Akli [(b) (6)]; Mellors, John W [(b) (6)]; Naimish Patel [(b) (6)]; Colvis, Christine (NIH/NCATS) [E] [(b) (6)]; Young, John [(b) (6)]; Stein, Peter (FDA/CDER) [(b) (6)]; Poole, Mike [(b) (6)]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [(b) (6)]; Vincent, Michael [(b) (6)]; Keith Gottesdiener [(b) (6)]; Elliott Levy [(b) (6)]; Wung, Peter /US [(b) (6)]; Koroshetz, Walter (NIH/NINDS) [E] [(b) (6)]; Higgs, Elizabeth (NIH/NIAID) [E] [(b) (6)]; Carlos O Garner [(b) (6)]
CC: Elizabeth Kim [(b) (6)]; Menetski, Joseph (FNIH) [T] [(b) (6)]; Salathin, Carla [(b) (6)]; [(b) (6)]; [(b) (6)]; [(b) (6)]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Wholley, David (FNIH) [T] [(b) (6)]; Melencio, Cheryl (FNIH) [T] [(b) (6)]; Lucas Smalldon [(b) (6)]; Walker, Paula (NIH/NINDS) [E] [(b) (6)]; Ward, Jackie (NIH/NINDS) [E] [(b) (6)]
Subject: HOLD for ACTIV Agent Prioritization Wave 1 Final Discussion Meeting
Location: [https://fnih.zoom.us/j,\(b\)\(6\)](https://fnih.zoom.us/j/(b)(6))
Start: 5/3/2020 7:00:00 PM
End: 5/3/2020 8:00:00 PM
Show Time As: Tentative

Required Attendees: Eric Hughes; Read, Sarah (NIH/NIAID) [E]; Ruxandra Draghia-Akli; John Mellors; Naimish Patel; Colvis, Christine (NIH/NCATS) [E]; Young, John; Stein, Peter (FDA/CDER); Poole, Mike; Buchman, Tim (OS/ASPR/BARDA) (CTR); Vincent, Michael; Keith Gottesdiener; Elliott Levy; Wung, Peter /US; Koroshetz, Walter (NIH/NINDS) [E]; Higgs, Elizabeth (NIH/NIAID) [E]; Carlos O Garner
Optional Attendees: Elizabeth Kim; Menetski, Joseph (FNIH) [T]; Salathin, Carla; [(b) (6)]; [(b) (6)]; Parker, Ashley (NIH/OD) [E]; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Lucas Smalldon; Walker, Paula (NIH/NINDS) [E]; Ward, Jackie (NIH/OD) [E] [(b) (6)]

Stacey Adam is inviting you to a scheduled Zoom meeting.

Join Zoom Meeting

[https://fnih.zoom.\(b\)\(6\)](https://fnih.zoom/(b)(6))

Meeting ID: [(b) (6)]

Password: [(b) (6)]

One tap mobile

[(b) (6)] US (Chicago)
[(b) (6)] US (New York)

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[(b) (6)] US (Chicago)
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Password: (b) (6)

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 6/26/2020 1:23:02 AM
To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; Sandeep Menon [(b) (6) Rachel Harrigan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=80023e7be2dd4554b54d1604fa60df18-rachel.h.ha]; Erhardt, William (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=86d3f82263b04011a1ff30220cd2d612-William.Erh]; Roger Paredes [(b) (6) Andrew Phillips [(b) (6)]]
CC: Demarcus [(b) (6)] Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [(b) (6)] Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Chen, Helen Q. [(b) (6)] Eron, Joseph J Jr [(b) (6)] Chew, Kara M.D. [(b) (6)] Daar, Eric [(b) (6)] rg]; Erhardt, William (HHS/IOS) [(b) (6)]

Subject: Canceled: ACTIV-3 Standing Protocol Team Meeting
Attachments: Untitled Attachment; Canceled: ACTIV-3 Writing Team; Untitled Attachment
Location: <https://fnih.zoom.us/> (b) (6)

Start: 6/29/2020 3:00:00 PM
End: 6/29/2020 4:00:00 PM
Show Time As: Free

Recurrence: Weekly
every Monday from 11:00 AM to 12:00 PM

Required Attendees: Jens Lundgren; Wentworth, Debby; (b) (6) (b) (6) Ajay Nirula - Lilly; (b) (6) Patterson, Amy (NIH/NHLBI) [E]; Andrew Phillips; (b) (6) (b) (6) Birgit Grund ((b) (6) (b) (6) Lane, Cliff (NIH/NIAID) [E]; (b) (6) (b) (6) Higgs, Elizabeth (NIH/NIAID) [E]; Emil (b) (6) (b) (6) Ginny Kan; Baker, Jason; (b) (6) (b) (6) Neaton, Jim; (b) (6) Judy Currier; (b) (6) (b) (6) Reineck, Lora (NIH/NHLBI) [E]; Kozak, Marina (OS/ASPR/BARDA); Miller, Marissa A (NIH/NHLBI) [E]; Mark Polizzotto; (b) (6) (b) (6) Proschan, Michael (NIH/NIAID) [E]; Aggarwal, Neil (NIH/NHLBI) [E]; Paul Klekotka - Lilly; Harrigan, Rachel (HHS/IOS); Cavan, Reilly; Roger Paredes; (b) (6) Read, Sarah (NIH/NIAID) [E]; Shweta Sharma; Taylor Thompson; (b) (6) (b) (6) Rosenberg, Yves (NIH/NHLBI) [E]; Davey, Victoria ((b) (6) Denning, Eileen; Larson, Gregg; Peter Smith, M.D. (Thoracic Surgery); Katharina Krapp; John Rule; Aileen M Ilaria
Optional Attendees: Daniel Dawson Murray; emilia. (b) (6) Lisbeth Jørgensen; Nicole Engen; RH-FP-CHIP-ACTIV3-INSIGHT014; Tierney, John (NIH/NIAID) [E]; Marie Helleberg; Cate Carey; Vjecha, Michael; Hudson, Fleur; Pett, Sarah; Bitten Aagaard; Charlotte Bjernved Nielsen; Kent P Hassett; Lilian Gonzalez; Andrew G Koustenis; Eccard-Koons, Vanessa (NIH) [C]; Buehn, Molly (NIH) [C]; MacDonald, Leah (NIH) [C]; Ganapathy Gopalrathnam; Janice Evans; Janelle A Sabo; Carlos O Garner - Lilly; Tonya L Combs; Lori J Stephens; Lau, Chuen-Yen (NIH/NIAID) [E]; Herpin, Betsey (NIH/NIAID) [E]; Barrett, Kevin (NIH/NIAID) [E]; Smolskis, Mary (NIH/NIAID) [E]; Engel, Theresa (NIH) [C]; Osborne, Cynthia (NIH) [C]; Simpson, Shelly (NIH) [C]; Vogel, Susan (NIH/NIAID) [E]; Grace, Beth (NIH/NIAID) [C]; Proffitt, Calvin (NIH) [C]; Hohn, Matt (NIH) [C]; (b) (6) McNay, Laura (NIH/NIAID) [E]; Pierson, Jerome (NIH/NIAID) [C]; Mock, Rebecca (NIH/NIAID) [E]; Segal Raim, Sharon (NIH) [E]; Miller, Tracey (NIH) [C]; Parrish, David (NIH/NIAID) [E]; Galcik, Michael (NIH) [C]; Dighero-Kemp, Bonnie (NIH/NIAID) [C]; Hensley, Lisa (NIH/NIAID) [E]

Stacey Adam is inviting you to a scheduled Zoom meeting.

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From: Adam, Stacey (FNIH) [T] [/o=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 12/18/2020 8:50:33 PM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Woodcock, Janet (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebfcf48879f92169bd7644e29-Janet.Woodc]; Marks, Gilbert (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60008133606b4f75835d3c77c2eeadb7-Gilbert.Mar]; Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Erbeling, Emily (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e976ebf7b14142fbb3c5c294efb334fe-erbelingej]; Eakin, Ann (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7dafba298c194f9d9bc13c54fe0cf29a-eakinae]; Erica Ollmann Saphire [(b) (6) Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Davey Smith [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4eb666cbbac44a1a53dde4e9816f51d-DaveySmith]; Kim, Peter (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c48148e476824ce893260acf33b0f774-kimp2]; Neaton, Jim [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7383b995f643442eb94c59697c2cbc29-neato001.um]; Lundgren, Jens [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=59d323d1d9274d84b8e8b3046cb81a6b-jens.lundgr]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Kiley, James (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=eae6b96b43b4dbcbff39382168a5c86-kileyj]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]
CC: Chen, Helen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8801b022ef974bf7bda8fd06f67002cf-qingchen.de]; Bugin, Kevin (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4e98409d40a4a9880bfb9f709481e7c-BUGINK.fda]; Carver, Trea (NIH) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac05f976df484ed69022b8663cd448d3-carverkr]; Reich, Colleen [(b) (6) ; Lisbeth Jørgensen [(b) (6) Rose Li Central Account [(b) (6) Dana Carluccio [(b) (6) Church, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d1761d52a54e4efa8c5f3f43dea3afaf-stanselleh]; Teyhen, Deydre (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c75b09732dc14cfcb346afd7671ee69f-Deydre.Teyh]; Sorosa, Alex David [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userffc6da86]; Erhardt, William (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=86d3f82263b04011a1ff30220cd2d612-William.Erh]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Jabarkhail, Mina [(b) (6) Harrigan, Rachel (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=41f4c4e7fa8c48359fe7fdcef26cbabc-Rachel.Harr]; Nasr, Hana
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userfe0939a1]

Subject: Canceled: ACTIV-2/-3 Trial Oversight Committee Meeting

Location: <https://fnih.zoom.us/> (b) (6)

Start: 12/23/2020 8:00:00 PM

End: 12/23/2020 9:00:00 PM

Show Time As: Free

Recurrence: Weekly

every Wednesday from 3:00 PM to 4:00 PM

Required Attendees: Wholley, David (FNIH) [T]; Woodcock, Janet (FDA/CDER); Marks, Gilbert (OS/ASPR/BARDA) (CTR); Bozzette, Sam (NIH/NCATS) [E]; Read, Sarah (NIH/NIAID) [E]; Lane, Cliff (NIH/NIAID) [E]; Erbelding, Emily (NIH/NIAID) [E]; Eakin, Ann (NIH/NIAID) [E]; Erica Ollmann Saphire; Stein, Peter (FDA/CDER); Judy Currier; Davey Smith; Kim, Peter (NIH/NIAID) [E]; (b) (6) (b) (6) Higgs, Elizabeth (NIH/NIAID) [E]; Kiley, James (NIH/NHLBI) [E]; Goff, David (NIH/NHLBI) [E]

Optional Attendees: Chen, Helen Q.; Bugin, Kevin (FDA/CDER); Carver, Trea (NIH) [C]; Reich, Colleen; Lisbeth Jørgensen; Rose Li Central Account; Dana Carluccio; Church, Elizabeth (NIH/NIAID) [E]; Teyhen, Deydre (HHS/IOS); Sorosa, Alex David; Erhardt, William (HHS/IOS); Melencio, Cheryl (FNIH) [T]; Parker, Ashley (NIH/OD) [E]; Jabarkhail, Mina; Harrigan, Rachel (HHS/IOS); Nasr, Hana

Dear ACTIV-2/-3 TOC Members,

Per my follow-up email just a few minutes ago, we will be canceling this meeting to allow time over the holidays for people to have less meetings. However, the TOC co-chairs reserve the right to call an Ad Hoc TOC meeting in the case of any urgent business needing to be discussed for the trials

Thanks,
Stacey

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Sent: 9/9/2020 1:02:44 PM
Subject: FW: Materials for September 9 ACTIV Executive Committee Teleconference
Attachments: 9.9 ACTIV Executive Committee Meeting 20200908_vFINAL.pdf; 2020-08-26_ACTIV_Leadership_Team_Meeting_vFinal.pdf; 2020-08-14_Executive_Committee_Meeting_Summary vFinal.pdf

From: Melencio, Cheryl (FNIH) [T] <(b) (6)> **On Behalf Of** Wholley, David (FNIH) [T]
Sent: Wednesday, September 9, 2020 8:53 AM
To: Collins, Francis (NIH/OD) [E] <(b) (6)> Disbrow, Gary (OS/ASPR/BARDA) <(b) (6)>
Dolsten, Mikael <(b) (6)> Fauci, Anthony (NIH/NIAID) [E] <(b) (6)> Gibbons, Gary (NIH/NHLBI) [E] <(b) (6)> Marks, Peter (FDA/CBER) <(b) (6)> Pao, William <(b) (6)> Plump, Andrew <(b) (6)> Stoffels, Paul <(b) (6)>
Woodcock, Janet (FDA/CDER) <(b) (6)> Colvis, Christine (NIH/NCATS) [E] <(b) (6)> Desrosiers, Betsy <(b) (6)> Eric Hughes <(b) (6)> Jansen, Kathrin <(b) (6)> Kurilla, Michael (NIH/NCATS) [E] <(b) (6)> Lowy, Douglas (NCI) <(b) (6)> Read, Sarah (NIH/NIAID) [E] <(b) (6)> Young, John <(b) (6)>
Cc: Anderson, James (NIH/OD) [E] <(b) (6)> Austin, Christopher (NIH/NCATS) [E] <(b) (6)> Burklow, John (NIH/OD) [E] <(b) (6)> Castillejos, Carlos <(b) (6)> Culp, Michelle (NIH/OD) [E] <(b) (6)> FNIH Central Account <(b) (6)> Freire, Maria (FNIH) [T] <(b) (6)> Gadbois, Ellen (NIH/OD) [E] <(b) (6)> Hallett, Adrienne (NIH/OD) [E] <(b) (6)> Lane, Cliff (NIH/NIAID) [E] <(b) (6)> Myles, Renate (NIH/OD) [E] <(b) (6)> Parker, Ashley (NIH/OD) [E] <(b) (6)> Tabak, Lawrence (NIH/OD) [E] <(b) (6)> Wolinetz, Carrie (NIH/OD) [E] <(b) (6)> Gorman, Greta (FNIH) [T] <(b) (6)> Meltzer, Abbey (FNIH) [T] <(b) (6)> Myles, Renate (NIH/OD) [E] <(b) (6)> Wolinetz, Carrie (NIH/OD) [E] <(b) (6)> Adam, Stacey (FNIH) [T] <(b) (6)> Alvarez, Rosa Maria <(b) (6)> Margaret Anderson <(b) (6)> Appell, Evan <(b) (6)> Chen, Helen Q. <(b) (6)> Elsaid, Olivia <(b) (6)> Gonzalez, Nina <(b) (6)> Hawk, Harrison <(b) (6)> Menetski, Joseph (FNIH) [T] <(b) (6)> Santos, Michael (FNIH) [T] <(b) (6)> Stratton, Benjamin <(b) (6)> btolman <(b) (6)> Tountas, Karen (FNIH) [T] <(b) (6)> Wachtel, Jonathan <(b) (6)> Wholley, David (FNIH) [T] <(b) (6)>
Subject: Materials for September 9 ACTIV Executive Committee Teleconference
Importance: High

Dear ACTIV EC members, Working Group Co-Chairs, and meeting participants:

Please see attached the PowerPoint slides, including the agenda, for our meeting (via Zoom) from **2:30 – 3:30 PM Eastern U.S. time** today. I have also attached notes from our August 26 Leadership Team meeting as well as our last EC meeting on August 14.

The Zoom information is:

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Please let Cheryl Melencio here at FNIH (copied) know if you are having any problems connecting. I look forward to a productive meeting.

APAR0000026139-2515773

Regards,

David

David Wholley
Senior Vice-President, Research Partnerships
Foundation for the National Institutes of Health

(b) (6)

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In 2019, the FNIH earned the highest rating from Charity Navigator for the fifth consecutive year and was recognized as an organization that exceeds industry standards.

From: Adam, Stacey (FNIH) [T] [/o=EXCHANGELABS/ou=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/cn=RECIPIENTS/cn=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 4/15/2020 12:47:26 PM
To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Amanda Peppercorn [(b) (6) Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Butterton, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fda]; Draghia-Akli, Ruxandra [(b) (6) Eisner, Mark [(b) (6) Gottesdiener, Keith [(b) (6) Hughes, Eric [(b) (6) Judy Carrier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Kim, Elizabeth [(b) (6) LaVange, Lisa [(b) (6) Levy, Elliot [(b) (6) Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Menon, Sandeep [Sandeep.M. (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Patel, Naimish [(b) (6) Peppercorn, Amanda [(b) (6) Poole, Mike [(b) (6) Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Price, Dionne (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a583eced842c44b18bb6fcd3820bee21-priced.fda]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]
CC: Biggs, Mary [(b) (6) Butcher, Tina [(b) (6) Demarcus [(b) (6) GMM [(b) (6) JKR [(b) (6) Macone, Erin [(b) (6) Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Peppercorn, Amanda [(b) (6) Salathin, Carla [(b) (6)
Subject: New NIH Database on COVID-19 Publications

Dear ACTIV TX-Clinical WG and Subgroups Members,

For your reference, since there has been much discussion about accessing early results finding in a quick way.

NIH is supporting a publication database on everything that has been published about COVID-19, generated by NIH Office of Portfolio Analysis (OPA).

- OPA has developed a comprehensive, human-curated portfolio of COVID 19 publications and preprints (<https://icite.od.nih.gov/covid19/search/>)
- This includes peer-reviewed articles from PubMed and preprints from medRxiv, bioRxiv, ChemRxiv, and arXiv. It is updated daily and enables users to leverage the iSearch platform to interrogate manually curated preprints, peer-reviewed publications, and all associated supplemental data from each

This provide an important functionality to cull through mountains of information that is in the public domain with simple search terms and ensure that the results you get back are definitively related to COVID-19.

Looking forward to seeing our Master Protocol Subgroup later today. Agenda and slides to come soon.

Thanks,
Stacey

Stacey J. Adam, PhD

Director, Cancer

Research Partnerships

Foundation for the National Institutes of Health

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From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 8/18/2020 3:07:28 PM
To: Brodd, Lauren (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ba665dea08e54171b3d6890c2518ddb9-leponelm]
Subject: Fwd: Notes from Friday's ACTIV Executive Committee & Working Group Co-chair Call
Attachments: image001.png; ATT00001.htm; 2020-08-14_Executive_Committee_Meeting_Summary vFinal.docx; ATT00002.htm

Begin forwarded message:

From: "Wholley, David (FNIH) [T]" <(b) (6)>
Date: August 18, 2020 at 9:16:02 AM EDT
To: "Collins, Francis (NIH/OD) [E]" <(b) (6)> "Disbrow, Gary (OS/ASPR/BARDA)" <(b) (6)> "Dolsten, Mikael" <(b) (6)> "Fauci, Anthony (NIH/NIAID) [E]" <(b) (6)> "Gibbons, Gary (NIH/NHLBI) [E]" <(b) (6)> "Marks, Peter (FDA/CBER)" <(b) (6)> "Pao, William" <(b) (6)> "Plump, Andrew" <(b) (6)> "Stoffels, Paul" <(b) (6)> "Woodcock, Janet (FDA/CDER)" <(b) (6)> "Colvis, Christine (NIH/NCATS) [E]" <(b) (6)> "Desrosiers, Betsy" <(b) (6)> Eric Hughes <(b) (6)> "Jansen, Kathrin" <(b) (6)> "Kurilla, Michael (NIH/NCATS) [E]" <(b) (6)> "Lowy, Douglas (NCI)" <(b) (6)> "Read, Sarah (NIH/NIAID) [E]" <(b) (6)> "Young, John" <(b) (6)>
Cc: "Adam, Stacey (FNIH) [T]" <(b) (6)> "Alvarez, Rosa" <(b) (6)> "Anderson, Margaret" <(b) (6)> "Chen, Helen" <(b) (6)> "Elsaid, Olivia" <(b) (6)> "Gonzalez, Nina" <(b) (6)> "Hawk, Harrison" <(b) (6)> "Menetski, Joseph (FNIH) [T]" <(b) (6)> "Santos, Michael (FNIH) [T]" <(b) (6)> "Stratton, Benjamin" <(b) (6)> "Tolman, Brett" <(b) (6)> "Tountas, Karen (FNIH) [T]" <(b) (6)> "Wachtel, Jonathan" <(b) (6)> "Wholley, David (FNIH) [T]" <(b) (6)> "Anderson, James (NIH/OD) [E]" <(b) (6)> "Austin, Christopher (NIH/NCATS) [E]" <(b) (6)> "Burklow, John (NIH/OD) [E]" <(b) (6)> "Castillejos, Carlos" <(b) (6)> "Culp, Michelle (NIH/OD) [E]" <(b) (6)> FNIH Central Account <(b) (6)> "Freire, Maria (FNIH) [T]" <(b) (6)> "Gadbois, Ellen (NIH/OD) [E]" <(b) (6)> "Hallett, Adrienne (NIH/OD) [E]" <(b) (6)> "Lane, Cliff (NIH/NIAID) [E]" <(b) (6)> "Myles, Renate (NIH/OD) [E]" <(b) (6)> "Parker, Ashley (NIH/OD) [E]" <(b) (6)> "Tabak, Lawrence (NIH/OD) [E]" <(b) (6)> "Wolinetz, Carrie (NIH/OD) [E]" <(b) (6)> "Melencio, Cheryl (FNIH) [T]" <(b) (6)>
Subject: Notes from Friday's ACTIV Executive Committee & Working Group Co-chair Call

Dear ACTIV Executive Committee Members and meeting attendees:

Please find attached the notes from our Friday, August 14 ACTIV Executive Committee meeting. As always, please email me with any concerns, questions, or additional comments.

Regards,
David

APAR0000010487-2515775

David Wholley
Senior Vice President, Research Partnerships
Foundation for the National Institutes of Health

(b) (6)

fnih.org

11400 Rockville Pike Suite 600 North Bethesda, MD 20852

Donate to the FNIH's Pandemic Response Fund to combat COVID-19: fnih.org/pandemic

From: Collins, Francis (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=410E1CA313F44CED9938E50D2FF0B6C2-COLLINSF]
Sent: 4/13/2020 2:07:56 AM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
Subject: RE: Other Companies to give a heads up

I sent notes to all of these except Scangos (since Vir was represented on April 3) and Reese (since Amgen has a rep already).

FC

From: Wholley, David (FNIH) [T] <(b) (6)>
Sent: Friday, April 10, 2020 11:03 AM
To: Collins, Francis (NIH/OD) [E] <(b) (6)>
Subject: RE: Other Companies to give a heads up

I think we have to be open if they specifically ask but am not sure I would specifically offer right off. Maybe say this is moving fast; you will keep them informed as the scope of this is refined but to let you know if they are interested in becoming more involved. For Reese and Kramer you can assume they already have representation of some sort.

From: Collins, Francis (NIH/OD) [E] <(b) (6)>
Sent: Friday, April 10, 2020 10:54 AM
To: Wholley, David (FNIH) [T] <(b) (6)>
Cc: Menetski, Joseph (FNIH) [T] <(b) (6)> Wood, Gretchen (NIH/OD) [E] <(b) (6)>
Subject: RE: Other Companies to give a heads up

Suggestions as to the message to convey? Are we open to adding other members to the WGs?

FC

From: Wholley, David (FNIH) [T] <(b) (6)>
Sent: Friday, April 10, 2020 10:40 AM
To: Collins, Francis (NIH/OD) [E] <(b) (6)>
Cc: Menetski, Joseph (FNIH) [T] <(b) (6)> ; Wood, Gretchen (NIH/OD) [E] <(b) (6)>
Subject: FW: Other Companies to give a heads up

Francis, here are the major folks to reach out to (thanks to Joe Menetski for this):

Regeneron - George Yancopoulos <(b) (6)>
Gilead - William Lee <(b) (6)>
Eisai - Lynn Kramer (was on Rupert Vessey's list of folks to include on TX list but we did not have room). He's VP, Chief Clinical Officer, Neurology Business Group <(b) (6)>
Biogen - Al Sandrock <(b) (6)>
Abbvie - Tom Hudson <(b) (6)>
Lilly - Dan Skovronsky <(b) (6)>
George Scangos (now at Vir) <(b) (6)>
Amgen - David Reese (you can thank him for participation of Elliott Levy (SVP Global Devt) on the TX-Therapeutics WG. He is part of the Vessey/Plump group but worth reaching out to directly—and a great partnership person, by the way) <(b) (6)>

Additions: Perhaps Stephane Bancel at Moderna, given the partnership with NIH? I have also not included anyone from Boehringer-Ingelheim or Bayer. Shall we try to get you those names and email addresses?

David

To: Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskiip]; (b) (6)

(b) (6) (b) (6) (b) (6) (b) (6)

(b) (6) Baric, Ralph [(b) (6) (b) (6) Ottinger, Elizabeth (NIH/NCATS [E] [(b) (6) Colvis, Christine (NIH/NCATS) [E] [(b) (6) Hewitt, Judith (NIH/NIAID) [E] [(b) (6) Deming, Damon (FDA/CDER) [(b) (6) (b) (6)

(b) (6) (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Collins, Francis (NIH/OD) [E] [(b) (6) (b) (6) Adams, Peter (OS/ASPR/BARDA) [(b) (6)]; Rao, Srinivas /US [(b) (6) Anderson, James (NIH/OD) [E] [(b) (6) Qashu, Felicia (NIH/OD) [E] [(b) (6) (b) (6)

Tomas Cihlar [(b) (6) (b) (6)

CC: Wholley, David (FNIH) [T] [(b) (6) Austin, Christopher (NIH/NCATS) [E] [(b) (6) Melencio, Cheryl (FNIH) [T] [(b) (6) Colvis, Christine (NIH/NCATS) [E] [(b) (6) Desrosiers, Betsy [(b) (6) Hughes, Eric [(b) (6) Jansen, Kathrin [(b) (6) Kurilla, Michael (NIH/NCATS) [E] [(b) (6) Lowy, Douglas (NCI) [(b) (6) Read, Sarah (NIH/NIAID) [E] [(b) (6) Tountas, Karen (FNIH) [T] [(b) (6) Santos, Michael (FNIH) [T] [(b) (6) Adam, Stacey (FNIH) [T] [(b) (6) James, Stephanie (FNIH) [T] [(b) (6) Alvarez, Rosa Maria [(b) (6) Kim, Elizabeth [(b) (6) Tolman, Brett [(b) (6) Wachtel, Jonathan [(b) (6)]; Prabhavathi Fernandes [(b) (6) Diamond, Michael [(b) (6) Rose Li [(b) (6) Dana Carluccio [(b) (6) Lagos, Enrique (NIH/NCATS) [E] [(b) (6) Jonson, Samantha (NIH/NCATS) [E] [(b) (6) Gonzalez, Nina [(b) (6) Simon, Dina (NIH/OD) [C] [(b) (6)]; Burrus-Shaw, Cyndi (NIH/OD) [E] [(b) (6) Rodriguez, Robin D [(b) (6) Dave Frankowski [(b) (6) Lowy, Douglas (NIH/NCI) [E] [(b) (6) Florence, Clint (NIH/NIAID) [E] [(b) (6)]; Louise Pitt [(b) (6) [(b) (6)

Start: 5/15/2020 3:00:00 PM

End: 5/15/2020 4:00:00 PM

Recurrence: (none)

Required Attendees: (b) (6) (b) (6) (b) (6) (b) (6)

(b) (6) (b) (6) (b) (6)

(b) (6) (b) (6) (b) (6) (b) (6)

(b) (6) (b) (6) (b) (6) (b) (6) Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; (b) (6) Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas /US; Anderson, James (NIH/OD) [E]; Qashu, Felicia (NIH/OD) [E]; Tomas Cihlar

From: Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415BB86087D08B628E6F-MELENCIOC]
Sent: 1/12/2021 10:03:14 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Bancel, Stephane [(b) (6) Carter, Kara [(b) (6) Cavaleri, Marco [(b) (6) Cihlar, Tomas [(b) (6)]; Collins, Francis (NIH/OD) [E] [(b) (6) Corey, Larry [(b) (6) Culp, Michelle (NIH/OD) [E] [(b) (6) Victoria Davey [(b) (6) Disbrow, Gary (OS/ASPR/BARDA) [(b) (6) Dolsten, Mikael [(b) (6) Erbeling, Emily (NIH/NIAID) [E] [(b) (6) Erck, Stan [(b) (6) Fauci, Anthony (NIH/NIAID) [E] [(b) (6) Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Gibbons, Gary (NIH/NHLBI) [E] [(b) (6) Hudson, Thomas [(b) (6) James, Stephanie (FNIH) [T] [(b) (6) Johnson, Robert (OS/ASPR/BARDA) [(b) (6)]; Kramer, Lynn [(b) (6) Lane, Cliff (NIH/NIAID) [E] [(b) (6) Lepore, John [(b) (6) Marks, Peter (FDA/CBER) [(b) (6)]; Mascola, John (NIH/VRC) [E] [(b) (6) Meeker, David [(b) (6) Menetski, Joseph (FNIH) [T] [(b) (6) Messonnier, Nancy (CDC/DDID/NCIRD/OD) [(b) (6) Pandya, Hitesh [hitesh. (b) (6) Pangalos, Mene [(b) (6) Pao, William [william. (b) (6) Parker, Ashley (NIH/OD) [E] [(b) (6)]; Perlmutter, Roger [(b) (6) Plenge, Robert [(b) (6) Plump, Andy [(b) (6) Rachel Ramoni [(b) (6) Reed, John [(b) (6) Reese, David [(b) (6) Rouse, Doris [(b) (6) Santos, Michael (FNIH) [T] [(b) (6) Skovronsky, Daniel [(b) (6) Stein, Peter (FDA/CDER) [(b) (6) Stoffels, Paul [(b) (6) Tabak, Lawrence (NIH/OD) [E] [(b) (6) Talley, Michael [(b) (6) Tsai, John [(b) (6) Vessey, Rupert [(b) (6) Virgin, Skip [(b) (6) Wholley, David (FNIH) [T] [(b) (6) Woodcock, Janet (FDA/CDER) [(b) (6) Young, John [(b) (6) Colvis, Christine (NIH/NCATS) [E] [(b) (6) Desrosiers, Betsy [(b) (6) Eric Hughes [(b) (6) Jansen, Kathrin [(b) (6) Kurilla, Michael (NIH/NCATS) [E] [(b) (6) Lowy, Douglas (NCI) [(b) (6) Read, Sarah (NIH/NIAID) [E] [(b) (6) Anderson, James (NIH/OD) [E] [(b) (6) Burklow, John (NIH/OD) [E] [(b) (6)]; Carluccio, Dana [(b) (6) Castillejos, Carlos [(b) (6) FNIH Central Account [(b) (6) Hallett, Adrienne (NIH/OD) [E] [(b) (6)]; Lumsden, Joanne (NIH/NCATS) [C] [(b) (6) Myles, Renate (NIH/OD) [E] [(b) (6) Wolinetz, Carrie (NIH/OD) [E] [(b) (6) Adam, Stacey (FNIH) [T] [(b) (6) Margaret Anderson [(b) (6) Appell, Evan [(b) (6) Chen, Helen [(b) (6) Connelly, Sarah [(b) (6) Gonzalez, Nina [(b) (6) Hawk, Harrison [(b) (6)]; Mendelson, Jesse [(b) (6) Nasr, Hana [(b) (6) Sorosa, Alex [(b) (6) Stratton, Benjamin [(b) (6) btolman [(b) (6) Wachtel, Jonathan [(b) (6) Meltzer, Abbey (FNIH) [T] [(b) (6) Embry, Alan (NIH/NIAID) [E] [(b) (6) Venkayya, Rajeev [(b) (6) Rutter, Joni (NIH/NCATS) [E] [(b) (6) Cwalina, Alex [(b) (6) Paul, Steve [(b) (6)]
CC: Austin, Sarah (NIH/NIAID) [E] [(b) (6) Barasch, Kimberly (NIH/NIAID) [C] [(b) (6) Bell, Julie [(b) (6) Burrus-Shaw, Cyndi (NIH/OD) [E] [(b) (6)]; Carver, Trea (NIH) [C] [(b) (6) Caulfied, Anita [(b) (6) Coan, Amanda [(b) (6) Conrad, Patricia (NIH/NIAID) [E] [(b) (6) Dimishkov, Roxanne (NIH/NHLBI) [C] [(b) (6)]; Edl, Susan [(b) (6)]; Fuhrer, Nicole [(b) (6) Giorgi, Sara [sara. (b) (6) Hoban, Michelle [(b) (6) Hoffstetter, Renata (FNIH) [T] [(b) (6) Iderdemaj, Vaide [(b) (6) Jenkins, Christine S. [(b) (6) Lever, Susan [susan. (b) (6) Magbie-Robinson, Kim (NIH/OD) [C] [(b) (6)]; Martin, Melisa [(b) (6) McManus, Ayanna (NIH/OD) [E] [(b) (6) Minnich, Beth [(b) (6) Perala, Mie [(b) (6) Protasiewicz, Ann [(b) (6) Riccobene, Kim [(b) (6) Riggins, Mary [(b) (6) Ripley, Nadege [(b) (6) Schuster, Donna [(b) (6) Sepulveda, Dorina (FNIH) [T] [(b) (6) Simon, Dina (NIH/OD) [C] [(b) (6)]

(b) (6) Suhana, Tina (NIH/VRC) [E] (b) (6); Thomas, Ashley (FDA/CDER)
(b) (6); Wood, Gretchen (NIH/OD) [E] (b) (6) Togashi, Mieko (NIH/NCI) [E]
(b) (6); Underwood, Nancy (b) (6) Zottoli, Jessica
(b) (6) Hughes, Karen (NIH/OD) [E] (b) (6); Regan, Donna M
(b) (6) Plenge, Robert (b) (6) Vessey, Rupert (b) (6)
Burke, Leslie (b) (6) Moghiminia, Mahtab (NIH/NCATS) [E] (b) (6)

Subject: ACTIV Leadership Team Call #17

Location: <https://fnih.zoom.us/> (b) (6)

Start: 6/28/2021 12:00:00 PM

End: 6/28/2021 1:30:00 PM

Show Time As: Tentative

Required Attendees: Bancel, Stephane; Carter, Kara; Cavaleri, Marco; Cihlar, Tomas; Collins, Francis (NIH/OD) [E]; Corey, Larry; Culp, Michelle (NIH/OD) [E]; Davey, Victoria; Disbrow, Gary (OS/ASPR/BARDA); Dolsten, Mikael; Erbeling, Emily (NIH/NIAID) [E]; Erck, Stan; Fauci, Anthony (NIH/NIAID) [E]; Gadbois, Ellen (NIH/OD) [E]; Gibbons, Gary (NIH/NHLBI) [E]; Hudson, Thomas; James, Stephanie (FNIH) [T]; Johnson, Robert (OS/ASPR/BARDA); Kramer, Lynn; Lane, Cliff (NIH/NIAID) [E]; Lepore, John; Marks, Peter (FDA/CBER); Mascola, John; Meeker, David; Menetski, Joseph (FNIH) [T]; Messonnier, Nancy (CDC/DDID/NCIRD/OD); Pandya, Hitesh; Pangalos, Mene; Pao, William; Parker, Ashley (NIH/OD) [E]; Paul, Steve; Perlmutter, Roger; Plenge, Robert; Plump, Andy; Ramoni, Rachel; Reed, John; Reese, David; Rouse, Doris; Santos, Michael (FNIH) [T]; Skovronsky, Daniel; Stein, Peter (FDA/CDER); Stoffels, Paul; Tabak, Lawrence (NIH/OD) [E]; Talley, Michael; Tsai, John; Vessey, Rupert; Virgin, Skip; Wholley, David (FNIH) [T]; Woodcock, Janet (FDA/OC); Young, John; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Anderson, James (NIH/OD) [E]; Burklow, John (NIH/OD) [E]; Carluccio, Dana; Castillejos, Carlos; FNIH Central Account; Hallett, Adrienne (NIH/OD) [E]; Lumsden, Joanne (NIH/NCATS) [C]; Myles, Renate (NIH/OD) [E]; Wolinetz, Carrie (NIH/OD) [E]; Adam, Stacey (FNIH) [T]; Anderson, Margaret; Appell, Evan; Chen, Helen; Connelly, Sarah; Gonzalez, Nina; Hawk, Harrison; Mendelson, Jesse; Nasr, Hana; Sorosa, Alex; Stratton, Ben; Tolman, Brett; Wachtel, Jonathan; Meltzer, Abbey (FNIH) [T]; Embry, Alan (NIH/NIAID) [E]; Venkayya, Rajeev; Rutter, Joni (NIH/NCATS) [E]; Cwalina, Alex

Optional Attendees: Austin, Sarah (NIH/NIAID) [E]; Barasch, Kimberly (NIH/NIAID) [E]; Bell, Julie; Burrus-Shaw, Cyndi (NIH/OD) [E]; Carver, Trea (NIH) [C]; Caulfield, Anita; Coan, Amanda; Conrad, Patricia (NIH/NIAID) [E]; Dimishkov, Roxanne (NIH/NHLBI) [C]; Edl, Susan; Fuhrer, Nicole; Giorgi, Sara; Hoban, Michelle; Hoffstetter, Renata (FNIH) [T]; Iberdemaj, Vaide; Jenkins, Christine S.; Krack, Kimberly; Lever, Susan; Magbie-Robinson, Kim (NIH/OD) [C]; Martin, Melisa; McManus, Ayanna (NIH/OD) [E]; Minnich, Beth; Perala, Mie; Protasiewicz, Ann; Riccobene, Kim; Riggan, Mary; Ripley, Nadege; Schuster, Donna; Sepulveda, Dorina (FNIH) [T]; Simon, Dina (NIH/OD) [C]; Suhana, Tina (NIH/VRC) [E]; Thomas, Ashley (FDA/CDER); Wood, Gretchen (NIH/OD) [E]; Togashi, Mieko (NIH/NCI) [E]; Underwood, Nancy; Zottoli, Jessica; Hughes, Karen (NIH/OD) [E]; Regan, Donna M; Plenge, Robert; Vessey, Rupert; Burke, Leslie; Moghiminia, Mahtab (NIH/NCATS) [E]

Joseph Menetski is inviting you to a scheduled Zoom meeting.

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Meeting ID: (b) (6)

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Name: ACTIV Working Group Co-chairs (CC)

Members: Colvis, Christine (NIH/NCATS) [E] (b) (6)

Desrosiers, Betsy (b) (6)

Hughes, Eric (b) (6)

Jansen, Kathrin (b) (6)

Kurilla, Michael (NIH/NCATS) [E] (b) (6)

Lowy, Douglas (NCI) (b) (6)

Read, Sarah (NIH/NIAID) [E] (b) (6)

Young, John (b) (6)

Holding time

Joseph Menetski is inviting you to a scheduled Zoom meeting.

Join Zoom Meeting

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(b) (6)

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US (New York)

Dial by your location

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US

US (Houston)

US (San Jose)

US (San Jose)

US

Meeting ID: (b) (6)

Password: (b) (6)

Find your local number: <https://zoom.us> (b) (6)

From: Myles, Renate (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7D317F5626934585B3692A1823C18522-MYLESR]
Sent: 4/16/2020 11:13:54 AM
To: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]
CC: Wolinetz, Carrie (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1c655040d47346c7b04d7bc11a403ecb-wolinetzcd]
Subject: FW: PLEASE READ: Draft Email to Collect Communication Contact Information

Hi Ashley:

I'm not sure if Francis added a Takeda contact to his email. I could not find one on the master contact list. I have not heard from their organizations yet. Would you let me know if you provided that to him last night or if they are missing from this email? Need to send it to this group this morning.

Thanks,
Renate

From: Myles, Renate (NIH/OD) [E]
Sent: Wednesday, April 15, 2020 9:11 PM
To: Collins, Francis (NIH/OD) [E] <(b) (6)>
Cc: Wood, Gretchen (NIH/OD) [E] <(b) (6)> McManus, Ayanna (NIH/OD) [E]
<(b) (6)> Burklow, John (NIH/OD) [E] ((b) (6) <(b) (6)> Parker, Ashley (NIH/OD) [E] <(b) (6)>
Subject: PLEASE READ: Draft Email to Collect Communication Contact Information
Importance: High

Hi Francis:

We need to collect the communication contacts from the partner organizations so we can share the release with them for review. Below is 1) a draft email for you to send to the company participants, 2) the contacts for the companies we list in the release except for Takeda (I could not find a Takeda contact on the master list; hoping Ashley can provide); 3) those who should be copied (feel free to add others).

Dear ACTIV colleagues:

As I mentioned earlier today, we would like to announce the plans for a public-private partnership as expeditiously as possible. Please provide the name of the most appropriate communication contact from your company so that we may share a draft of the embargoed press release for your review. Please send the contact information to Renate Myles at (b) (6) and Abbey Meltzer ((b) (6) this evening, if possible.

BCC: (b) (6)

CC: (b) (6)

Thanks,
Renate

Sent: 11/23/2020 4:33:43 PM
Subject: FW: Notes from Thursday's ACTIV Leadership Team Meeting
Attachments: 2020-11-19_ACTIV_Leadership_Team_Meeting_Summary_v3.docx

From: Melencio, Cheryl (FNIH) [T] <(b) (6)> **On Behalf Of** Wholley, David (FNIH) [T]
Sent: Monday, November 23, 2020 11:18 AM
To: Austin, Christopher (NIH/NCATS) [E] <(b) (6)> Bancel, Stephane
<(b) (6)> Carter, Kara <(b) (6)> Cavaleri, Marco
<(b) (6)> Cihlar, Tomas <(b) (6)> Collins, Francis (NIH/OD) [E]
<(b) (6)> Corey, Larry <(b) (6)> Culp, Michelle (NIH/OD) [E] <(b) (6)>
Victoria Davey <(b) (6)> Disbrow, Gary (OS/ASPR/BARDA) <(b) (6)> Dolsten, Mikael
<(b) (6)> Erbeling, Emily (NIH/NIAID) [E] <(b) (6)> Erck, Stan
<(b) (6)> Fauci, Anthony (NIH/NIAID) [E] <(b) (6)> Freire, Maria (FNIH) [T]
<(b) (6)> Gadbois, Ellen (NIH/OD) [E] <(b) (6)> Gibbons, Gary (NIH/NHLBI) [E]
<(b) (6)> Hudson, Thomas <(b) (6)> James, Stephanie (FNIH) [T]
<(b) (6)> Johnson, Robert (OS/ASPR/BARDA) <(b) (6)> Kramer, Lynn
<(b) (6)> Lane, Cliff (NIH/NIAID) [E] <(b) (6)> Lepore, John <(b) (6)>
Marks, Peter (FDA/CBER) <(b) (6)> Marston, Hilary (NIH/NIAID) [E] <(b) (6)>
Mascola, John (NIH/VRC) [E] <(b) (6)> Meeker, David <(b) (6)> Menetski, Joseph
(FNIH) [T] <(b) (6)> Messonnier, Nancy (CDC/DDID/NCIRD/OD) <(b) (6)> Pandya, Hitesh
<(b) (6)> Pangalos, Mene <(b) (6)> Pao, William
<(b) (6)> Parker, Ashley (NIH/OD) [E] <(b) (6)> Paul, Steve <(b) (6)>
Perlmutter, Roger <(b) (6)> Plenge, Robert <(b) (6)> Plump, Andy
<(b) (6)> Rachel Ramoni <(b) (6)> Reed, John <(b) (6)> Reese,
David <(b) (6)> Rouse, Doris <(b) (6)> Santos, Michael (FNIH) [T] <(b) (6)>
Skovronsky, Daniel <(b) (6)> Stein, Peter (FDA/CDER) <(b) (6)> Stoffels, Paul
<(b) (6)> Tabak, Lawrence (NIH/OD) [E] <(b) (6)> Talley, Michael
<(b) (6)> Tsai, John <(b) (6)> Vessey, Rupert <(b) (6)> Virgin, Skip
<(b) (6)> Wholley, David (FNIH) [T] <(b) (6)> Woodcock, Janet (FDA/CDER)
<(b) (6)> Young, John <(b) (6)> Colvis, Christine (NIH/NCATS) [E]
<(b) (6)> Desrosiers, Betsy <(b) (6)> Eric Hughes
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<(b) (6)> Lowy, Douglas (NCI) <(b) (6)> Read, Sarah (NIH/NIAID) [E] <(b) (6)>
Young, John <(b) (6)>
Cc: Anderson, James (NIH/OD) [E] <(b) (6)> Burklow, John (NIH/OD) [E] <(b) (6)>
Carluccio, Dana <(b) (6)> Castillejos, Carlos <(b) (6)> FNIH Central Account
<(b) (6)> Gadbois, Ellen (NIH/OD) [E] <(b) (6)> Hallett, Adrienne (NIH/OD) [E]
<(b) (6)> Lane, Cliff (NIH/NIAID) [E] <(b) (6)> Parker, Ashley (NIH/OD) [E]
<(b) (6)> Tabak, Lawrence (NIH/OD) [E] <(b) (6)> Wolinetz, Carrie (NIH/OD) [E]
<(b) (6)> Gorman, Greta (FNIH) [T] <(b) (6)> Meltzer, Abbey (FNIH) [T]
<(b) (6)> Myles, Renate (NIH/OD) [E] <(b) (6)> Wolinetz, Carrie (NIH/OD) [E]
<(b) (6)> Adam, Stacey (FNIH) [T] <(b) (6)> Margaret Anderson
<(b) (6)> Appell, Evan <(b) (6)> Chen, Helen Q. <(b) (6)>
Connelly, Sarah <(b) (6)> Gonzalez, Nina <(b) (6)> Hawk, Harrison
<(b) (6)> Mendelson, Jesse <(b) (6)> Menetski, Joseph (FNIH) [T]
<(b) (6)> Santos, Michael (FNIH) [T] <(b) (6)> asorosa <(b) (6)> Stratton,
Benjamin <(b) (6)> btolman <(b) (6)> Tountas, Karen (FNIH) [T]
<(b) (6)> Wachtel, Jonathan <(b) (6)> Wholley, David (FNIH) [T] <(b) (6)>
Subject: Notes from Thursday's ACTIV Leadership Team Meeting

Dear Leadership Team members and meeting attendees:

Please see the notes from our teleconference this past Thursday, November 19. Please let me know any additional comments, questions, or suggestions regarding these notes or the action items.

Thank you again for all your support of and contributions to ACTIV.

Regards,

David

David Wholley
Senior Vice-President, Research Partnerships
Foundation for the National Institutes of Health

(b) (6)

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11400 Rockville Pike Suite 600 North Bethesda, MD 20852

In 2019, the FNIH earned the highest rating from Charity Navigator for the fifth consecutive year and was recognized as an organization that exceeds industry standards.

From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 5/7/2020 8:58:53 PM
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CC: Mary Biggs [(b) (6) Demarcus [(b) (6) Macone, Erin (b) (6)]; Tountas, Karen (FNIH) [T] [(b) (6) Wachtel, Jonathan [(b) (6) Elizabeth Kim [(b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Butcher, Tina [(b) (6) Wholley, David (FNIH) [T] [(b) (6) Melencio, Cheryl (FNIH) [T] [(b) (6) Forster, Katherine [(b) (6)]
Subject: ACTIV TX-Clinical Master Protocol Subgroup Meeting #16
Location: [https://fnih.zoom.us/j/ \(b\) \(6\)](https://fnih.zoom.us/j/ (b) (6))
Start: 5/13/2020 5:00:00 PM
End: 5/13/2020 6:00:00 PM
Show Time As: Busy

Required Attendees: Bozzette, Sam (NIH/NCATS) [E]; Joan Butterson; Collins, Sylva (FDA/CDER); Judy Currier; De Claro, R. Angelo (FDA/CDER); Mark Eisner; Keith Gottesdiener; Eric Hughes; Lisa LaVange; Elliott Levy; Sandeep Menon; Amanda Peppercorn; Proschan, Michael (NIH/NIAID) [E]; Read, Sarah (NIH/NIAID) [E]; Amanda Peppercorn; Price, Dionne (FDA/CDER); Rubin, Daniel B. (FDA/CDER); Shen, Yuan Li (FDA/CDER); Farley, John (FDA/CDER); Goff, David (NIH/NHLBI) [E]; Vincent, Michael; Wung, Peter /US; Karen Lynn Price; Pamela Tenaerts, M.D.; Patterson, Amy (NIH/NHLBI) [E]; Esserman, Laura; Higgs, Elizabeth (NIH/NIAID) [E]; James Palazzolo; Burgess, Timothy; Beumont-Mauviel, Maria [JRDUS]; Peeters, Monika [JRDUS]; Woodfall, Brian [JRDUS]; Van Heeswijk, Rolf [JRDUS]
Optional Attendees: Mary Biggs; Demarcus; Macone, Erin; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley (NIH/OD) [E]; Butcher, Tina; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Forster, Katherine

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 5/15/2020 7:21:09 PM
To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Bozzette, Sam (NIH/NCATS) [E] [(b) (6) Butterson, Joan [(b) (6) Judy Currier [(b) (6) Eric Hughes [eric. (b) (6) LaVange, Lisa M [(b) (6) Read, Sarah (NIH/NIAID) [E] (b) (6) Karen Lynn Price [(b) (6) Higgs, Elizabeth (NIH/NIAID) [E] [(b) (6) Woodcock, Janet (FDA/CDER) [(b) (6) Stein, Peter (FDA/CDER) [(b) (6) Carlos O Garner [(b) (6) Bugin, Kevin (FDA/CDER) [(b) (6) Marks, Gilbert (OS/ASPR/BARDA) (CTR) [G (b) (6)
CC: Demarcus [(b) (6) Tountas, Karen (FNIH) [T] [(b) (6) Wachtel, Jonathan [(b) (6) Elizabeth Kim [(b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]
Subject: ACTIV TX-Clinical Master Protocol mAbs Steering Committee - ACTIV2 Synopsis Review
Attachments: 5401 Protocol Synopsis 051920v3.docx
Location: <https://fnih.zoom.us/> (b) (6)
Start: 5/20/2020 5:00:00 PM
End: 5/20/2020 6:00:00 PM
Show Time As: Busy

Required Attendees: Bozzette, Sam (NIH/NCATS) [E]; Joan Butterson; Judy Currier; Eric Hughes; Lisa LaVange; Read, Sarah (NIH/NIAID) [E]; Karen Lynn Price; Higgs, Elizabeth (NIH/NIAID) [E]; Woodcock, Janet (FDA/CDER); Stein, Peter (FDA/CDER); Carlos O Garner; Bugin, Kevin (FDA/CDER); Marks, Gilbert (OS/ASPR/BARDA) (CTR)
Optional Attendees: Demarcus; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley (NIH/OD) [E]

Dear ACTIV TX-Clinical Master Protocol mAbs Steering Committee,

Please find attached the synopsis of the outpatient protocol for review at our meeting today. This was assembled by the ACTG group based on our writing team conversations and then edited a bit by Lisa and Karen for the statistical sections.

This document is NOT ready to share beyond this group yet, but could be gotten ready in short turn if needed for the company summit, Janet. We will just need to know when that is.

Finally, we will be discussing the selection of the inpatient network for the companion protocol today.

Thanks,

Stacey

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 6/26/2020 1:23:02 AM
To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Jim Neaton [(b) (6) Jens Lundgren [(b) (6) Eric Hughes [(b) (6) Read, Sarah (NIH/NIAID) [E] [(b) (6) Higgs, Elizabeth (NIH/NIAID) [E] [(b) (6) Kozak, Marina (OS/ASPR/BARDA) [(b) (6) Patterson, Amy (NIH/NHLBI) [E] [amy.patterson@nih.gov]; Aggarwal, Neil (NIH/NHLBI) [E] [(b) (6)]; Reineck, Lora (NIH/NHLBI) [E] [(b) (6) Judy Currier [(b) (6) Karen Lynn Price [(b) (6) LaVange, Lisa M [(b) (6) Sandeep Menon [(b) (6) Proschan, Michael (NIH/NIAID) [E] [proschan@niaid.nih.gov]; Miller, Marissa A (NIH/NHLBI) [E] [(b) (6) Rachel Harrigan [(b) (6) Erhardt, William (HHS/IOS) [(b) (6) [(b) (6) Gelijns, Annetine [(b) (6) ; Moskowitz, Alan [(b) (6) Ab Babiker [(b) (6) Cavan, Reilly [(b) (6) Phillips, Andrew [(b) (6) [(b) (6) Birgit Grund [(b) (6) Neaton, Jim [(b) (6) Joe Koopmeiners [(b) (6) David Vock [(b) (6) Thomas Murray [(b) (6) Max Parmar [(b) (6) Mark Polizzotto [(b) (6) .au]; Ginny Kan [Virginia. (b) (6) Lane, Cliff (NIH/NIAID) [E] [(b) (6) Baker, Jason [(b) (6) Roger Paredes [(b) (6) [(b) (6) [(b) (6) [(b) (6) [(b) (6) Rosenberg, Yves (NIH/NHLBI) [E] [(b) (6) ; Emilia. [(b) (6) [(b) (6) Ajay Nirula [(b) (6) Paul Klekotka [(b) (6) Ginde, Adit [(b) (6) [(b) (6) Wentworth, Debby [(b) (6) Shweta Sharma [(b) (6) vdavey@mail.va.gov; Denning, Eileen [(b) (6) Demarcus [(b) (6) Tountas, Karen (FNIH) [T] [(b) (6) Wachtel, Jonathan [(b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Chen, Helen Q. [(b) (6) Chew, Kara M.D. [(b) (6) Daar, Eric [(b) (6) Bagiella, Emilia [(b) (6) [(b) (6) Lisbeth Jørgensen [(b) (6) Erhardt, William (HHS/IOS) [(b) (6) [(b) (6) Harrigan, Rachel (HHS/IOS) [(b) (6) Eron, Joseph J Jr [(b) (6)]

Subject: ACTIV-3 Writing Team

Attachments: Untitled Attachment

Location: <https://fnih.zoom.us/> (b) (6)

Start: 6/29/2020 3:00:00 PM

End: 6/29/2020 4:00:00 PM

Show Time As: Busy

Recurrence: Weekly
every Monday from 11:00 AM to 12:00 PM

Required Attendees: Adam, Stacey (FNIH) [T]; Jim Neaton; Jens Lundgren; Eric Hughes; Read, Sarah (NIH/NIAID) [E]; Higgs, Elizabeth (NIH/NIAID) [E]; Kozak, Marina (OS/ASPR/BARDA); Patterson, Amy (NIH/NHLBI) [E]; Aggarwal, Neil (NIH/NHLBI) [E]; Reineck, Lora (NIH/NHLBI) [E]; Judy Currier; Karen Lynn Price; Lisa LaVange; Sandeep Menon; Proschan, Michael (NIH/NIAID) [E]; Miller, Marissa A (NIH/NHLBI) [E]; Rachel Harrigan; Erhardt, William (HHS/IOS); [(b) (6) Gelijns, Annetine; Moskowitz, Alan; Ab Babiker; Cavan, Reilly; Phillips, Andrew [(b) (6) Birgit Grund; Neaton, Jim; Joe Koopmeiners; David Vock; Thomas Murray; Max Parmar; Mark Polizzotto; Ginny Kan; Lane, Cliff (NIH/NIAID) [E]; Baker, Jason; Roger Paredes; [(b) (6) [(b) (6) [(b) (6) [(b) (6) Rosenberg, Yves (NIH/NHLBI) [E]; [(b) (6) jessica. [(b) (6) Ajay Nirula; Paul Klekotka; Ginde, Adit; Andrew Phillips; [(b) (6) Wentworth, Debby; Shweta Sharma; [(b) (6) Denning, Eileen

Optional Attendees: Demarcus; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Parker, Ashley (NIH/OD) [E]; Chen, Helen Q.; Eron, Joseph J Jr; Chew, Kara M.D.; Daar, Eric; Bagiella, Emilia; chip-activ3-insight014.rigshospitalet@regionh.dk; Lisbeth Jørgensen; Erhardt, William (HHS/IOS); (b) (6) Harrigan, Rachel (HHS/IOS)

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 4/16/2020 10:28:41 PM
To: Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; Collins, Sylvia (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylvia.Coll]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Mark Eisner [(b) (6) Keith Gottesdiener [(b) (6) Eric Hughes [(b) (6) LaVange, Lisa M [(b) (6) Elliott Levy [(b) (6) Sandeep Menon [(b) (6) Amanda Peppercorn [(b) (6) Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Amanda Peppercorn [(b) (6) Price, Dionne (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a583eced842c44b18bb6fcd3820bee21-priced.fda]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Farley, John (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40b4c4456b14464788f31fe7bcaa09bc-FARLEYJ.fda]
CC: Mary Biggs [(b) (6) Demarcus [(b) (6) Macone, Erin [(b) (6) Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [(b) (6) Elizabeth Kim [(b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Rose Li Central Account [(b) (6) Lucas Smalldon [(b) (6) Butcher, Tina [(b) (6) Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Wung, Peter /US [(b) (6)

Subject: ACTIV Therapeutics-Clinical Master Protocol Subgroup - Meeting #4

Location: [https://fnih.zoom. \(b\) \(6\)](https://fnih.zoom. (b) (6))

Start: 4/23/2020 6:00:00 PM

End: 4/23/2020 7:00:00 PM

Show Time As: Tentative

Required Attendees: Bozzette, Sam (NIH/NCATS) [E]; Joan Butterson; Collins, Sylvia (FDA/CDER); Judy Currier; De Claro, R. Angelo (FDA/CDER); Mark Eisner; Keith Gottesdiener; Eric Hughes; Lisa LaVange; Elliott Levy; Sandeep Menon; Amanda Peppercorn; Proschan, Michael (NIH/NIAID) [E]; Read, Sarah (NIH/NIAID) [E]; Amanda Peppercorn; Price, Dionne (FDA/CDER); Rubin, Daniel B. (FDA/CDER); Shen, Yuan Li (FDA/CDER); Farley, John (FDA/CDER)

Optional Attendees: Mary Biggs; Demarcus; Macone, Erin; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley (NIH/OD) [E]; Rose Li Central Account; Lucas Smalldon; Butcher, Tina; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Wung, Peter /US

Dear TX-Clinical Master Protocol Subgroup,

This will be our 4th meeting. We will update with materials closer to the meeting.

Thanks,

Stacey

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 4/17/2020 1:48:20 PM
To: Amanda Peppercorn [(b) (6)] Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Draghia-Akli, Ruxandra [(b) (6)] Eisner, Mark [(b) (6)] Gottesdiener, Keith [(b) (6)] Hughes, Eric [(b) (6)] Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Kim, Elizabeth [(b) (6)] LaVange, Lisa [(b) (6)] Levy, Elliot [(b) (6)] Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Menon, Sandeep [(b) (6)] Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkera]; Patel, Naimish [(b) (6)] Peppercorn, Amanda [(b) (6)] Poole, Mike [(b) (6)] Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Collins, Sylvia (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylva.Colli]
CC: (b) (6)
Subject: Sharing of the Press Release on ACTIV

Dear ACTIV Therapeutics-Clinical WG,

In case you have not already seen this, I wanted to share with you the press release that was sent today from NIH.

The NIH has issued its press release: <https://www.nih.gov/news-events/news-releases/nih-launch-public-private-partnership-speed-covid-19-vaccine-treatment-options>

Thanks again for all your efforts to this!

Stacey

NIH to launch public-private partnership to speed COVID-19 vaccine and treatment options
Health agencies, leading pharmaceutical companies to join forces to accelerate pandemic response

The National Institutes of Health and the Foundation for the NIH (FNIH) are bringing together more than a dozen leading biopharmaceutical companies, the Health and Human Services Office of the Assistant Secretary for Preparedness and Response, the Centers for Disease Control and Prevention, the U.S. Food and Drug Administration and the European Medicines Agency to develop an international strategy for a coordinated research response to the COVID-19 pandemic. The planned Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) partnership will develop a collaborative framework for prioritizing vaccine and drug candidates, streamlining clinical trials, coordinating regulatory processes and/or leveraging assets among all partners to rapidly respond to the COVID-19 and future pandemics. This is part of the whole-of-government, whole-of-America response the Administration has led to beat COVID-19.

"We need to bring the full power of the biomedical research enterprise to bear on this crisis," said NIH Director Francis S. Collins, M.D., Ph.D. "Now is the time to come together with unassailable objectivity to swiftly advance the development of the most promising vaccine and therapeutic candidates that can help end the COVID-19 global pandemic."

Coordinated by the FNIH, ACTIV government and industry partners will provide infrastructure, subject matter expertise and/or funding (both new and in-kind) to identify, prioritize and facilitate the entry of some of the most promising candidates into clinical trials. Industry partners also will make available certain prioritized compounds, some of which have already cleared various phases of development, and associated data to support research related to COVID-19. The partnership is being developed with input from a steering committee managed by the FNIH which includes leaders from NIH, FDA and the research and development organizations of the companies.

"COVID-19 is the most significant global health challenge of our lifetime, and it will take all of us working together as a global community to put an end to this pandemic," said Paul Stoffels, M.D., Vice Chairman of the Executive Committee and Chief Scientific Officer, Johnson & Johnson. "We will need to harness the best ideas from multiple stakeholders, including governments, regulatory authorities, academia, NGOs and industry to stop COVID-19. At Johnson & Johnson, we are committed to working closely with FNIH, IMI and are part of other important consortia to speed solutions to stop this pandemic."

"Battling the COVID-19 pandemic is far too great a challenge for any one company or institution to solve alone," said Mikael Dolsten, M.D., Ph.D., Chief Scientific Officer and President, Worldwide Research, Development and Medical, Pfizer. "We are seeing an unprecedented level of collaboration across the innovation ecosystem to address this global health crisis, and this potentially powerful NIH initiative may allow us to further accelerate the delivery of much needed therapies to patients around the world."

The research community is currently striving to sift through more than 100 potential preventives and therapeutics for COVID-19. ACTIV will aim to provide guidance which can be used to prioritize the plethora of vaccine and therapeutic candidates in development and connect clinical trial networks to test new and repurposed candidates quickly and efficiently.

"Using the most advanced clinical trial methods to rapidly test multiple interventions will help get the answers we need as soon as possible to expedite potential prevention and treatment approaches to fight COVID-19," said FDA Commissioner Stephen M. Hahn, M.D. "Collaboration is a critical ingredient for success and the FDA will continue to

Participating Organizations

Government

- National Institutes of Health
- HHS Office of the Assistant Secretary for Preparedness and Response
- U.S. Food and Drug Administration
- Centers for Disease Control and Prevention
- European Medicines Agency

Non-Profit

- Foundation for the National Institutes of Health

Industry

- AbbVie
- Amgen
- AstraZeneca
- Bristol Myers Squibb
- Evotec
- GlaxoSmithKline
- Johnson & Johnson
- KSQ Therapeutics
- Eli Lilly and Company
- Merck & Co., Inc.
- Novartis
- Pfizer
- Roche
- Sanofi
- Takeda
- Vir Biotechnology

use every tool possible under our Coronavirus Treatment Acceleration Program to speed the development of safe and effective medical countermeasures.”

ACTIV will have four fast-track focus areas, each of which will be led by a highly motivated working group of senior scientists representing government, industry and academia:

1) *Standardize and share preclinical evaluation methods in an open forum that allows for comparison and validation by:*

- Establishing a centralized process and repository for harmonizing and sharing methods and evaluating models
- Extending access to high-throughput screening facilities, especially in biosafety level-3 laboratories, with a goal of testing all compounds that have been in human clinical trials to identify the potential to apply these compounds to COVID-19
- Increasing access to validated animal models
- Enhancing comparison of approaches to identify informative assays

1) *Prioritize and accelerate clinical evaluation of therapeutic candidates with near-term potential by:*

- Establishing a steering committee with relevant expertise and objectivity to set criteria for and rank potential candidates submitted by industry partners for first wave and subsequent evaluation
- Developing a complete inventory of potential candidates with different mechanisms of action and acceptable safety profiles
- Designing, launching and openly sharing master protocols with agreed upon endpoints, sampling and analysis for evaluating candidates
- Using a single control arm to enhance trial efficiency

2) *Maximize clinical trial capacity and effectiveness by:*

- Connecting existing networks of clinical trials to build capacity and capabilities, including specialization in different populations and disease stages
- Leveraging infrastructure and expertise from across NIH networks, including:
 - Adjuvant Discovery and Adjuvant Development Programs
 - AIDS Clinical Trials Network
 - Clinical and Translational Science Awards Program
 - Clinical Trials in Organ Transplantation
 - Cooperative Centers on Human Immunology
 - HIV Prevention Trials Network
 - HIV Vaccine Trials Network
 - Human Immunology Project Consortium
 - International Network for Strategic Initiatives for Global HIV Trials (INSIGHT) Network
 - National Cancer Institute Clinical Oncology Research Program
 - National Cancer Institute Clinical Trial Network
 - Prevention and Early Treatment of Acute Lung Injury (PETAL) Clinical Trials Network
 - Strategies to Innovate EmeRgENcy Care Clinical Trials Network (SIREN)
 - T and B Cell Discovery Programs and Immune Epitope Database
 - Vaccine Treatment and Evaluation Units
- Establishing a coordination mechanism across networks to expedite trials, track incidence across sites and project future capacity

3) *Advance vaccine development by:*

- Creating a collaborative framework to share insights into natural immunity and vaccine candidate-induced immune response by:
 - Mapping epitopes and developing assays
 - Establishing protocols for sampling and immunological analyses and reagents
 - Collecting clinical data on immunological responses and endpoints, to enable meta-analysis of correlates of protection
 - Engaging with regulators on surrogate endpoints for clinical evaluation

“This powerful public-private partnership will focus and expedite R&D activities required to combat COVID-19,” says Maria C. Freire, Ph.D., President and Executive Director, FNIH. “Working in lock-step, the public and private sectors will maximize the chances of success and provide a roadmap to pre-emptively manage future threats.”

About the Foundation for the National Institutes of Health: The Foundation for the National Institutes of Health creates and manages alliances with public and private institutions in support of the mission of the NIH, the world’s premier medical research agency. The Foundation, also known as the FNIH, works with its partners to accelerate biomedical research and strategies against diseases and health concerns in the United States and across the globe. The FNIH organizes and administers research projects; supports education and training of new researchers; organizes educational events and symposia; and administers a series of funds supporting a wide range of health issues. Established by Congress in 1990, the FNIH is a not-for-profit 501(c)(3) charitable organization. For additional information about the FNIH, please visit fnih.org.

About the National Institutes of Health (NIH): NIH, the nation’s medical research agency, includes 27 Institutes and Centers and is a component of the U.S. Department of Health and Human Services. NIH is the primary federal agency conducting and supporting basic, clinical, and translational medical research, and is investigating the causes, treatments, and cures for both common and rare diseases. For more information about NIH and its programs, visit www.nih.gov.

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Director, Cancer

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[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user706e5647]; Kim, Elizabeth [(b) (6) btolman [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user7b137a1e]; Wachtel, Jonathan (b) (6) Prabhavathi Fernandes [(b) (6) Diamond, Michael [(b) (6) Rose Li [(b) (6) Dana Carluccio [(b) (6) Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagoses]; Jonson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Rodriguez, Robin D [(b) (6) Dave Frankowski [david. (b) (6) Baric, Toni C [(b) (6) Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; Florence, Clint (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Nancy Haigwood [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=03d589f440d84691ac0a530e4ba6ceb5-haigwoon.oh]; Stratton, Benjamin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=usere3ed7188]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Hawk, Harrison [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user280c84f8]; Mason, Stephen [(b) (6) (b) (6) Connelly, Sarah [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3ed93bab]; (b) (6)

Subject: ACTIV Preclinical full working group

Dear All,

We will be cancelling the preclinical full working group meeting on Nov 18th and will be using this time for a subgroup discussion of immediate need.

We will get together the 25th as normal to catch up before the Holiday.

Best regards,
Joe

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
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To: Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterton, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; Collins, Sylva (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylva.Colli]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Mark Eisner [(b) (6) Keith Gottesdiener [(b) (6) Eric Hughes [(b) (6) LaVange, Lisa M [(b) (6) Elliott Levy [(b) (6) Sandeep Menon [(b) (6) Amanda Peppercorn [(b) (6) Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Amanda Peppercorn [(b) (6)
CC: Mary Biggs [(b) (6) Demarcus [(b) (6) Macone, Erin [erinm@amgen.com]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [(b) (6) Elizabeth Kim [(b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Rose Li Central Account [(b) (6) Lucas Smalldon [(b) (6) Butcher, Tina [(b) (6)
Subject: ACTIV TX-Clinical WG Master Protocol Subgroup -1st Meeting

Dear ACTIV Therapeutics-Clinical WG,

Thank you for your interest and participation in the Master Protocol sub-group. We are appreciative of your time and look forward to a focused discussion on the development of COVID-19 Master Protocols.

Our first meeting will take place today, **Wednesday April 15th** from **1:30pm-2:30pm ET**. Dial-in instructions are below, similar to the zoom call on Monday. We wanted to notify you promptly of the meeting time and will follow up with an agenda and any necessary materials prior to the call.

Please note that this is not a fixed timeslot for upcoming sub-group meetings. After this first sub-group meeting, we will send out a scheduling link to coordinate the best time for sub group meetings moving forward.

Kind regards,
Stacey, on behalf of the ACTIV TX-Clinical WG

Join Zoom Meeting

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Meeting ID: (b) (6)

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(b) (6) US (New York)

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Director, Cancer

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Sent: 7/22/2020 5:55:50 PM
To: Brodd, Lauren (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ba665dea08e54171b3d6890c2518ddb9-leponelm]
Subject: FW: Summary of Communications Rollout plan for ACTIV clinical trials
Attachments: Summary_Rollout_ACTIV_Tx_Vaccines_7.22.2020.docx

FYI

From: Melencio, Cheryl (FNIH) [T] <(b) (6)> **On Behalf Of** Wholley, David (FNIH) [T]
Sent: Wednesday, July 22, 2020 1:50 PM
To: Austin, Christopher (NIH/NCATS) [E] <(b) (6)> Bancel, Stephane
<(b) (6)> Carter, Kara <(b) (6)> Cavaleri, Marco
<(b) (6)> Cihlar, Tomas <(b) (6)> Collins, Francis (NIH/OD) [E]
<(b) (6)> Corey, Larry <(b) (6)> Culp, Michelle (NIH/OD) [E] <(b) (6)>
Disbrow, Gary (OS/ASPR/BARDA) <(b) (6)> Dolsten, Mikael <(b) (6)> Erbeling, Emily (NIH/NIAID) [E] <(b) (6)> Erck, Stan <(b) (6)> Fauci, Anthony (NIH/NIAID) [E]
<(b) (6)> Freire, Maria (FNIH) [T] <(b) (6)> Gadbois, Ellen (NIH/OD) [E]
<(b) (6)> Gibbons, Gary (NIH/NHLBI) [E] <(b) (6)> Hudson, Thomas
<(b) (6)> James, Stephanie (FNIH) [T] <(b) (6)> Johnson, Robert (OS/ASPR/BARDA)
<(b) (6)> Kramer, Lynn <(b) (6)> Lane, Cliff (NIH/NIAID) [E] <(b) (6)>
Lepore, John <(b) (6)> Marks, Peter (FDA/CBER) <(b) (6)> Marston, Hilary (NIH/NIAID) [E] <(b) (6)> Mascola, John (NIH/VRC) [E] <(b) (6)> Meeker, David
<(b) (6)> Menetski, Joseph (FNIH) [T] <(b) (6)> Messonnier, Nancy (CDC/DDID/NCIRD/OD)
<(b) (6)> Pandya, Hitesh <(b) (6)> Pangalos, Mene
<(b) (6)> Pao, William <(b) (6)> Parker, Ashley (NIH/OD) [E]
<(b) (6)> Paul, Steve <(b) (6)> Perlmutter, Roger <(b) (6)>
Plenge, Robert <(b) (6)> Plump, Andy <(b) (6)> Rachel Ramoni
<(b) (6)> Rasi, Guido <(b) (6)> Reed, John <(b) (6)> Reese, David
<(b) (6)> Rouse, Doris <(b) (6)> Santos, Michael (FNIH) [T] <(b) (6)> Skovronsky, Daniel <(b) (6)>
<(b) (6)> Stein, Peter (FDA/CDER) <(b) (6)> Stoffels, Paul
<(b) (6)> Tabak, Lawrence (NIH/OD) [E] <(b) (6)> Talley, Michael
<(b) (6)> Tsai, John <(b) (6)> Vessey, Rupert <(b) (6)> Virgin, Skip
<(b) (6)> Wholley, David (FNIH) [T] <(b) (6)> Woodcock, Janet (FDA/CDER)
<(b) (6)> Young, John <(b) (6)> Colvis, Christine (NIH/NCATS) [E]
<(b) (6)> Desrosiers, Betsy <(b) (6)> Eric Hughes
<(b) (6)> Jansen, Kathrin <(b) (6)> Kurilla, Michael (NIH/NCATS) [E]
<(b) (6)> Lowy, Douglas (NCI) <(b) (6)> Read, Sarah (NIH/NIAID) [E] <(b) (6)>
Young, John <(b) (6)>
Cc: Anderson, James (NIH/OD) [E] <(b) (6)> Burklow, John (NIH/OD) [E] <(b) (6)>
Castillejos, Carlos <(b) (6)> Hallett, Adrienne (NIH/OD) [E] <(b) (6)> Myles, Renate (NIH/OD) [E] <(b) (6)>
<(b) (6)> Wolinetz, Carrie (NIH/OD) [E] <(b) (6)> Adam, Stacey (FNIH) [T]
<(b) (6)> Alvarez, Rosa <(b) (6)> Anderson, Margaret <(b) (6)>
Chen, Helen <(b) (6)> Elsaid, Olivia <(b) (6)> Gonzalez, Nina
<(b) (6)> James, Stephanie (FNIH) [T] <(b) (6)> Menetski, Joseph (FNIH) [T]
<(b) (6)> Santos, Michael (FNIH) [T] <(b) (6)> Stratton, Ben <(b) (6)>
Tolman, Brett <(b) (6)> Tountas, Karen (FNIH) [T] <(b) (6)> Wachtel, Jonathan
<(b) (6)> Wholley, David (FNIH) [T] <(b) (6)> Meltzer, Abbey (FNIH) [T]
<(b) (6)> Gorman, Greta (FNIH) [T] <(b) (6)>
Subject: Summary of Communications Rollout plan for ACTIV clinical trials

Dear Leadership Team members and associated staff:

As noted on our last Leadership Team call we are planning to begin launching shortly a series of master protocols designed or otherwise supported through ACTIV to test therapeutics and vaccines for COVID-19. Attached is the current draft summary of the communications plan for all of these activities. As noted, it will consist initially of a "treatment page" on the NIH ACTIV website that will provide an updated on ACTIV's progress and a general preview of the protocols that are planned, which will then be followed by a rollout of individual specific press releases and other media on each master protocol as it actually launches.

Although the NIH Communications team is working with the individual companies whose drugs are being tested to review detailed materials as they are created, they will not have time or resources to seek detailed feedback on the wording of press materials from every partner involved in ACTIV. However, you may share this summary with your organization's communications staff and they may contact Renate Myles (b) (6) at NIH if they have any questions.

We look forward to what should be a very exciting month for ACTIV!

Regards,
David Wholley

David Wholley
Senior Vice-President, Research Partnerships
Foundation for the National Institutes of Health
(b) (6)
fnih.org
11400 Rockville Pike Suite 600 North Bethesda, MD 20852

In 2019, the FNIH earned the highest rating from Charity Navigator for the fifth consecutive year and was recognized as an organization that exceeds industry standards.

To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Rachel Harrigan [(b) (6) Ab Babiker (b) (6) Neaton, Jim (b) (6) Thomas Murray [(b) (6) LaVange, Lisa M [(b) (6) Max Parmar [(b) (6) Birgit Grund [(b) (6) Lane, Cliff (NIH/NIAID) [E] [(b) (6)]; David Vock [(b) (6) Aggarwal, Neil (NIH/NHLBI) [E] [(b) (6)]; (b) (6) Ginny Kan [(b) (6) (b) (6) Read, Sarah (NIH/NIAID) [E] [(b) (6) Paul Klekotka [(b) (6) (b) (6) Phillips, Andrew (b) (6) [(b) (6) Rosenberg, Yves (NIH/NHLBI) [E] [(b) (6) Roger Paredes [(b) (6) (b) (6) Shweta Sharma [(b) (6) Moskowitz, Alan [(b) (6) Wentworth, Debby [(b) (6) Higgs, Elizabeth (NIH/NIAID) [E] [(b) (6) Joe Koopmeiners [(b) (6) Gelijns, Annetine [(b) (6) Erhardt, William (HHS/IOS) [(b) (6) Cavan, Reilly [(b) (6) Jens Lundgren [(b) (6) (b) (6) Kozak, Marina (OS/ASPR/BARDA) [(b) (6) Baker, Jason [(b) (6) (b) (6) (b) (6) Judy Currier (b) (6) Miller, Marissa A (NIH/NHLBI) [E] [(b) (6) (b) (6) Patterson, Amy (NIH/NHLBI) [E] [(b) (6) Ginde, Adit [(b) (6) Mark Polizzotto [(b) (6) Denning, Eileen [(b) (6) Proschan, Michael (NIH/NIAID) [E] [(b) (6) Jim Neaton [(b) (6) Sandeep Menon [(b) (6) Karen Lynn Price [(b) (6) (b) (6) Ajay Nirula [(b) (6) Eric Hughes [(b) (6) Reineck, Lora (NIH/NHLBI) [E] (b) (6) [(b) (6) Harrigan, Rachel (HHS/IOS) [(b) (6) Chen, Helen Q. [(b) (6) Demarcus [(b) (6) Bagiella, Emilia [(b) (6) chip-activ3- (b) (6) Wachtel, Jonathan (b) (6) Erhardt, William (HHS/IOS) [(b) (6) Tountas, Karen (FNIH) [T] [(b) (6) Lisbeth Jørgensen [(b) (6) Daar, Eric [(b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Chew, Kara M.D. [(b) (6) Eron, Joseph J Jr [(b) (6)]

Attachments: ACTIV_TX-Clinical_ACTIV-3 Writing Team Meeting Agenda_20200629.pdf

Start: 6/29/2020 4:00:00 PM

End: 6/29/2020 5:00:00 PM

Show Time As: Busy

Recurrence: (none)

Required Attendees: Ab Babiker; Neaton, Jim; Thomas Murray; Lisa LaVange; Max Parmar; Birgit Grund; Lane, Cliff (NIH/NIAID) [E]; David Vock; Rachel Harrigan; Aggarwal, Neil (NIH/NHLBI) [E]; (b) (6) Ginny Kan; (b) (6) Read, Sarah (NIH/NIAID) [E]; Paul Klekotka; (b) (6) Phillips, Andrew (b) (6) Rosenberg, Yves (NIH/NHLBI) [E]; Roger Paredes; (b) (6) Shweta Sharma; Moskowitz, Alan; Wentworth, Debby; Higgs, Elizabeth (NIH/NIAID) [E]; Joe Koopmeiners; Gelijns, Annetine; Erhardt, William (HHS/IOS); Cavan, Reilly; Andrew Phillips; Jens Lundgren; (b) (6) Kozak, Marina (OS/ASPR/BARDA); Baker, Jason; (b) (6) (b) (6) Judy Currier; Miller, Marissa A (NIH/NHLBI) [E]; (b) (6) .au; Patterson, Amy (NIH/NHLBI) [E]; Ginde, Adit; Mark Polizzotto; Denning, Eileen; Proschan, Michael (NIH/NIAID) [E]; Jim Neaton; Sandeep Menon; Karen Lynn Price; (b) (6) Ajay Nirula; Eric Hughes; Reineck, Lora (NIH/NHLBI) [E]

Optional Attendees: Chen, Helen Q.; Demarcus; Bagiella, Emilia; (b) (6) (b) (6) Wachtel, Jonathan; Erhardt, William (HHS/IOS); Tountas, Karen (FNIH) [T]; Lisbeth Jørgensen; Daar, Eric; Parker, Ashley (NIH/OD) [E]; Eron, Joseph J Jr; Chew, Kara M.D.; Harrigan, Rachel (HHS/IOS)

Dear ACTIV-3 Writing Team,

Please find attached a high level agenda for tomorrow's call from 12-1pm ET.

APAR0000019723-2515799

Thanks,
Stacey

Join Zoom Meeting
<https://fnih.zoom.us/>

(b) (6)

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Password: (b) (6)

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US (San Jose)
US (San Jose)

Meeting ID: (b) (6)

Password: (b) (6)

Find your local number: <https://fnih.zoom.u>

(b) (6)

To: Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Qashu, Felicia (NIH/OD) [E] [(b) (6)]; (b) (6) (b) (6) (b) (6)
(b) (6) (b) (6) (b) (6) (b) (6)
(b) (6) Baric, Ralph [(b) (6) (b) (6) Ottinger, Elizabeth (NIH/NCATS) [E] [(b) (6) Colvis, Christine (NIH/NCATS) [E] [(b) (6) Hewitt, Judith (NIH/NIAID) [E] [(b) (6) ; Deming, Damon (FDA/CDER) [(b) (6) (b) (6)
(b) (6) (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Collins, Francis (NIH/OD) [E] [(b) (6) (b) (6) Adams, Peter (OS/ASPR/BARDA) [(b) (6) Rao, Srinivas /US [(b) (6) Anderson, James (NIH/OD) [E] [(b) (6) Tomas Cihlar [(b) (6)
CC: Nancy Haigwood [(b) (6) Hild, Sheri (NIH/OD) [E] [(b) (6) Diamond, Michael [(b) (6) Florence, Clint (NIH/NIAID) [E] [(b) (6) Wholley, David (FNIH) [T] [(b) (6) Austin, Christopher (NIH/NCATS) [E] [(b) (6) Melencio, Cheryl (FNIH) [T] [(b) (6) Colvis, Christine (NIH/NCATS) [E] [(b) (6) Desrosiers, Betsy [(b) (6) Hughes, Eric [(b) (6) Jansen, Kathrin [(b) (6) Kurilla, Michael (NIH/NCATS) [E] [(b) (6)]; Lowy, Douglas (NCI) [(b) (6) Read, Sarah (NIH/NIAID) [E] [(b) (6) Tountas, Karen (FNIH) [T] [(b) (6) Santos, Michael (FNIH) [T] [(b) (6) Adam, Stacey (FNIH) [T] [(b) (6) James, Stephanie (FNIH) [T] [(b) (6) Alvarez, Rosa Maria [(b) (6) Kim, Elizabeth [(b) (6) Tolman, Brett [(b) (6) Wachtel, Jonathan [(b) (6)]; Prabhavathi Fernandes [(b) (6) Rose Li [(b) (6) Dana Carluccio [(b) (6) Lagos, Enrique (NIH/NCATS) [E] [(b) (6)]; Jonson, Samantha (NIH/NCATS) [E] [(b) (6) Gonzalez, Nina [(b) (6) Simon, Dina (NIH/OD) [C] [(b) (6) Burrus-Shaw, Cyndi (NIH/OD) [E] [(b) (6) Rodriguez, Robin D [(b) (6) Dave Frankowski [(b) (6) Lowy, Douglas (NIH/NCI) [E] [(b) (6) Louise Pitt ((b) (6) [(b) (6) Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA) [(b) (6)

Start: 5/29/2020 3:00:00 PM
End: 5/29/2020 4:00:00 PM

Recurrence: (none)

Required Attendees: (b) (6) (b) (6) (b) (6) (b) (6)
(b) (6) (b) (6) (b) (6) (b) (6)
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(b) (6) (b) (6) (b) (6) (b) (6)
(b) (6) Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E];
(b) (6) Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas /US; Anderson, James (NIH/OD) [E]; Tomas Cihlar; Qashu, Felicia (NIH/OD) [E]

Optional Attendees: Diamond, Michael; Florence, Clint (NIH/NIAID) [E]; Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski; Lowy, Douglas (NIH/NCI) [E]; Louise Pitt ((b) (6) Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA); Nancy Haigwood; Hild, Sheri (NIH/OD) [E]

Sent: 7/9/2020 8:35:40 PM

Hi Francis,

Please see draft notes below to invite the CEO's for Moderna and Novavax to the leadership team meetings.

Thanks,
Ashley

To: (b) (6)
Cc: Wholley, David (FNIH) [T] (b) (6)

Dear Stephane,

Thank you for recommending Tal Zaks for the ACTIV vaccines working group. We have lots of activity across our ACTIV working groups moving at rapid speed. ACTIV has a leadership team that meets once a month to discuss progress and we typically invite the CEO's of the biotech companies to join. It would be great to have you join future meetings to represent Moderna as a partner.

Please let me know if you would be able to join our leadership team and I will ensure you receive the meeting invite for our next meeting scheduled for Wednesday, July 29, 2:30-4:00pm.

Thanks,
Francis

Francis Collins M.D., Ph.D.
NIH Director

To: (b) (6)
Cc: Wholley, David (FNIH) [T] (b) (6)

Dear Stanley,

I greatly appreciate Gregory Glenn serving on the ACTIV vaccines working group as a representative for Novavax. We have lots of activity across our ACTIV working groups moving at rapid speed. ACTIV has a leadership team that meets once a month to discuss progress and we typically invite the CEO's of the biotech companies to join. It would be great to have you join future meetings to represent Novavax as a partner.

Please let me know if you would be able to join our leadership team and I will ensure you receive the meeting invite for our next meeting scheduled for Wednesday, July 29, 2:30-4:00pm.

Thanks,
Francis

Francis Collins M.D., Ph.D.
NIH Director

From: Vincent, Michael [(b) (6)]
Sent: 4/17/2020 2:28:47 AM
To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Eric Hughes [(b) (6)]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Ruxandra Draghia-Akli [(b) (6)]; Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Naimish Patel [(b) (6)]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Young, John [(b) (6)]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Poole, Mike [(b) (6)]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]
CC: Elizabeth Kim [(b) (6)]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Alvarez, Rosa Maria [(b) (6)]; Salathin, Carla [(b) (6)]; (b) (6); (b) (6); (b) (6); Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Lucas Smalldon [(b) (6)]
Subject: Re: [EXTERNAL] Time Sensitive: Review and Feedback Needed for Agent Prioritization Subgroup
Attachments: image001.jpg; image002.jpg; image003.jpg; image004.jpg

Hi Stacey. I think the spreadsheet looks pretty comprehensive. One feature I liked from the ACCORD filtering process was the classification of primary MOA, although I'm not sure I'd agree with their category labels (Innate immunity, immune modulators, etc) and how they lumped things. Right now we have MOA/Rationale (column F), which I think should be 2 columns. For example, MOA might be S1P1 inhibitor, and rationale might be lymphocyte trafficking inhibitor (some integrin blockers would share the same rationale).

Another column that might be helpful is hypothesis monitorability. There may be biomarker endpoints that could be addressed with relatively small sample sizes for a given rationale. For example, a rationale that should lead to CRP or ferritin reduction could be assessed for futility with a relatively small sample size relative to a rationale that can only be assessed by reduction of progression to ventilation.

Another suggested addition would be to call out 'risks' in addition to known safety findings. The latter would have been defined in different populations, but theoretical risks may be clear in this population – potential to inhibit viral clearance for many of the immune targets. Monitorability of the risks might also be a column - ability to measure viral load for immune targets, compared to another mechanism with a theoretical risk that can't be easily monitored (e.g., blockade of alveolar macrophage function for anti-GM-CSF).

For your 2 questions:

I would be happy to participate in the prioritization process.

PhD in pharmacology, MD, rheumatologist, expertise in translational immunology, clinical pharmacology, and clinical development of diverse immunomodulators.

Thanks, Mike

Michael Vincent, MD PhD
SVP and CSO, I&I RU
Pfizer, Inc.
1 Portland St.

Cambridge, MA 02139

Cell: (b) (6)

From: "Adam, Stacey (FNIH) [T]" <(b) (6)>

Date: Thursday, April 16, 2020 at 4:48 PM

To: Eric Hughes <(b) (6)>, "Read, Sarah (NIH/NIAID) [E]" <(b) (6)>, Ruxandra Draghia-Akli <(b) (6)>, "Mellors, John W" <(b) (6)>, Naimish Patel <(b) (6)>, "Colvis, Christine (NIH/NCATS) [E]" <(b) (6)>, "Young, John" <(b) (6)>, "Stein, Peter (FDA/CDER)" <(b) (6)>, "Poole, Mike" <(b) (6)>, "Buchman, Tim (OS/ASPR/BARDA)" <(b) (6)>, First Last <(b) (6)>

Cc: Elizabeth Kim <(b) (6)>, "Menetski, Joseph (FNIH) [T]" <(b) (6)>, "Alvarez, Rosa Maria" <(b) (6)>, "Salathin, Carla" <(b) (6)>, <(b) (6)>, <(b) (6)>, "Parker, Ashley (NIH/OD) [E]" <(b) (6)>, "Wholley, David (FNIH) [T]" <(b) (6)>, "Melencio, Cheryl (FNIH) [T]" <(b) (6)>, Lucas Smalldon <(b) (6)>

Subject: [EXTERNAL] Time Sensitive: Review and Feedback Needed for Agent Prioritization Subgroup

Dear ACTIV TX-Clinical Agent Prioritization Subgroup,

First, thank you all for attending the WG call today. As discussed, please find attached again the DRAFT Prioritization Criteria broken out into data fields in this Excel spreadsheet. We really would like to hear your feedback on these fields and if they are the right ones and comprehensive.

Second, we have decided that if we can get **response from at least 75% of you by 6am tomorrow (04/16/2020)** on this document that **we will not have a need to meet tomorrow**, but can regroup again on Monday. **Until then I am placing a HOLD on your calendar for the meeting.** Therefore, if you could please email me that you have reviewed this document and let me what your feedback is. **Please respond, even just to say no changes or looks good.**

Finally, the co-chairs have begun to discuss how we should find individuals to perform the review. **We envision that we will need specific areas of expertise based on our first WG conversation; therefore, please let us the answer to the following two questions:**

1. **Do you wish to participate in the agent prioritization process? YES/NO**
2. **If yes, could you please provide us with what you feel your specific expertise is?**

This second question will allow us to determine we need to recruit other reviewers. We do envision segmenting the lists into small groups for review initially based on expertise and agents. Then we would have those smaller groups report to the larger team for final prioritization assessment.

Thanks again for all your efforts!

Kind regards,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
Foundation for the National Institutes of Health
Direct: (b) (6) | Mobile: (b) (6)
fnih.org

11400 Rockville Pike, Suite 600, North Bethesda, MD 20852



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APAR0000023398-2515802

From: Myles, Renate (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7D317F5626934585B3692A1823C1B522-MYLESR]
Sent: 5/18/2020 1:15:33 PM
To: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Pollock, Rachel (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4887cb3513e242dfa7d2df712dcc6d6a-pollockrc]; Wooldridge, Shannon (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=385b0c281f104789873e956dc91b7c06-burdense]
Subject: RE: Time sensitive: Making your ACTIV Participation Public

Hi Rachel and Shannon:

Would you check FC's mailbox for this information ASAP? We need to launch the webpage this morning.

Thanks,
Renate

From: Parker, Ashley (NIH/OD) [E] <(b) (6)>
Sent: Monday, May 18, 2020 7:57 AM
To: Myles, Renate (NIH/OD) [E] <(b) (6)> Pollock, Rachel (NIH/OD) [E] <(b) (6)>
Wooldridge, Shannon (NIH/OD) [E] <(b) (6)>
Subject: Re: Time sensitive: Making your ACTIV Participation Public

Hi Renate, Rachel, and Shannon,

We've made lots of progress! Shannon — can we see if the 3 ACTIV participants responded to Dr. Collins privately over the weekend?

Thank you,
Ashley

On May 17, 2020, at 11:15 PM, Myles, Renate (NIH/OD) [E] <(b) (6)> wrote:

Hi Ashley and Rachel:

Below are the three people I did not hear from. I searched my inbox. Just wanted to double check that they didn't just respond to Francis. Thanks, Renate

Ralph Baric, Ph.D.

William R. Kenan, Jr., Distinguished Professor, Department of Epidemiology
Professor, Department of Microbiology and Immunology
University of North Carolina, Gillings School of Global Public Health
(b) (6)

Damon Deming, Ph.D.

Virologist, Division of Antiviral Products, Office of New Drugs
U.S. Food and Drug Administration
(b) (6)

Kathrin Jansen, Ph.D.

Senior Vice President and Head of Vaccine Research and Development
Pfizer

(b) (6)

From: Collins, Francis (NIH/OD) [E] (b) (6)

Sent: Thursday, May 14, 2020 11:00 AM

To: Collins, Francis (NIH/OD) [E] (b) (6)

Cc: Myles, Renate (NIH/OD) [E] (b) (6); Meltzer, Abbey (FNIH) [T] (b) (6);

Wholley, David (FNIH) [T] (b) (6)

Subject: Time sensitive: Making your ACTIV Participation Public

Dear ACTIV Colleagues:

Yes, this message is for you, though your address was in the bcc line!

NIH would like to launch an ACTIV webpage to provide stakeholders with a central resource for information about our efforts, including announcements, scientific papers, and new developments. Currently, the content is based on publicly available information, but we would like add the ACTIV leadership and working group members. Your representation on ACTIV demonstrates the breadth and depth of expertise and experience from all sectors committed to this effort. **Please send your responses to me, cc'ing Renate Myles, Abbey Meltzer, and David Wholley by 12:00 p.m. ET tomorrow, Friday, May 15, if you agree to be listed on the web site as part of the ACTIV team.**

Thanks,
Francis

Francis S. Collins, MD, PhD
NIH Director

Sent: 6/18/2020 12:07:43 PM
To: Brodd, Lauren (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ba665dea08e54171b3d6890c2518ddb9-leponelm]
Subject: RE: ACTIV rosters for website

Hi Lauren,

Thank you for doing this – I will follow up with Cheryl to see if we can get more information on the discrepancies you've identified.

Please see additional responses in red below.

From: Brodd, Lauren (NIH/OD) [E] <(b) (6)>
Sent: Wednesday, June 17, 2020 6:42 PM
To: Parker, Ashley (NIH/OD) [E] <(b) (6)>
Subject: ACTIV rosters for website

Hi Ashley,

I compared the WG rosters (using file "ACTIV Working Group Rosters- MASTER" from Cheryl's email yesterday, below and attached) to the website. Few things:

- **Preclinical Working Group:** Damon Deming is listed on the Master excel file, but not on the website.
- **Therapeutics Clinical Working Group:** David Goff and Yves Rosenberg are both listed on the website, but not in the Master excel file.
 - Note: on the website, David Goff is listed for both the Therapeutics Clinical and the Clinical Trial Capacity WGs (not on both in the excel sheet).
- **Vaccines Working Group:** Gregory Glenn is listed on the Master excel file, but not on the website.
- The only addition for WG members that I have seen through email is Therese Takas. She is both listed in the excel file and on the website.
- I compared the names listed in the ACTIV WG Rosters- MASTER file with the website. Is there anything else I should be looking for/comparing aside from the names of WG members (such as members of the leadership/executive committees, or participating companies)? Yes, please compare the EC members listed and company names with those listed on the website – ACTIVleadership is not listed on the website. And do I need to do anything with the "Master and WG Email list for ACTIV" file? I think it would be useful to update the current master email spreadsheet or create a new one to include 1. EC tab (name, position, company, and email), 2. leadership tab (name, position, company, and email), and 3. company only tab with list of alphabetized company names – this will make it easier to compare moving forward. It may also be a good idea to make sure the names/emails in the master match those listed for the working group rosters (they are prepared by different staff at FNIH and we've had issues with those not matching previously).

Thanks,

Lauren

From: Melencio, Cheryl (FNIH) [T] (b) (6)
Sent: Tuesday, June 16, 2020 8:59 AM
To: Parker, Ashley (NIH/OD) [E] (b) (6) >
Cc: Brodd, Lauren (NIH/OD) [E] (b) (6)
Subject: RE: Intro to Lauren Brodd

Nice to meet you Lauren. Enclosed are the spreadsheets and I will send them each Friday.

Cheryl

Cheryl Melencio

Administrative Manager, Research Partnerships

Foundation for the National Institutes of Health

(b) (6)

fnihi.org

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Donate to the FNIH's Pandemic Response Fund to combat COVID-19: fnihi.org/pandemic



From: Parker, Ashley (NIH/OD) [E] <(b) (6)>

Sent: Tuesday, June 16, 2020 8:56 AM

To: Melencio, Cheryl (FNIH) [T] (b) (6)

Cc: Brodd, Lauren (NIH/OD) [E] (b) (6)

Subject: Intro to Lauren Brodd

Good morning Cheryl,

I hope you are off to a great start this week! I want to virtually introduce you to Lauren Brodd, cc'd here – Lauren will be working with Renate and myself on the ACTIV communications for the NIH website. I would like to ensure that she also receives the updates for members who are added to the working groups and companies who may continue to join – this will help us with keeping our website up to date.

I informed Lauren of our weekly receipt of the two spreadsheets, one with emails that you've managed and the other with the list of working groups managed by the FNIH COMMs. If you could share any updates to these spreadsheets that would be great (these were last received on June 3rd) and we will look forward to our regular updates on Fridays.

Thank you,
Ashley

Ashley Parker, Ph.D.

Special Assistant to the NIH Director for Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV)

Office of the Director | National Institutes of Health

Tel: (b) (6)



National Institutes of Health

To: King, James (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce1f3853e43d4463a04f7d74992f96ac-James.King.]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Bascles, Lionel [(b) (6) Cohen, Myron [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2141b9e28c1a421fb3c1c4f75dd4c457-myron_cohen]; Corey, Larry [lcorey@fredhutch.org]; Desrosiers, Betsy [(b) (6) Dickens, Jim (NIH/NCATS) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12591c90404e46caba73079cf4a5e2ea-dickensj]; Doroshov, James (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a1d0fb9f055940c39b387cae2485faa6-doroshovj]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Kurilla, Michael (NIH/NCATS) [E] [(b) (6) Nayak, Seema (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=51d5ee6848004578b5bf9c808eca8f6f-nayaksu]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Payton, Manizhe (NIH/NIAID) [E] [(b) (6) Resnansky, Laura [(b) (6) Srinivasan, Badhri [(b) (6) Wachtel, Jonathan [(b) (6)]; Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Vincent, Mike [(b) (6) Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]

CC: Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Jansen, Kathrin [(b) (6) Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Young, John [(b) (6) Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; Anderson, Margaret [(b) (6) Carluccio, Dana [(b) (6) Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Gonzalez, Nina [(b) (6) Heaton, Penny [(b) (6) James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Li, Rose [(b) (6) Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Tuveson, Nancy [(b) (6) Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Criffield, Robin [(b) (6) Minnich, Beth [(b) (6) Katz, Rebecca (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8e2b174d9bf748e9aa5ed901b4c5a3d9-katzrd]; Stratton, Benjamin [(b) (6) Tolman, Brett [(b) (6) Victoria Davey [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c8291f38ec342f895243c0617e115ec-victoria.da]; Jintanat Ananworanich [(b) (6) Sizemore, Christine (NIH/FIC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=05494833e0fc47a9acac194cd338b201-csizemore]; Kenny, Dermot [(b) (6) Weinmann, Gail (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f38a543b4021483ba67e42af1165dcad-weinmang]; Garner, Carlos [(b) (6) Hughes, Eric [(b) (6) Hamilton, Nancy [(b) (6)

Attachments: Clinical Trial Capacity Working Group Meeting Agenda_05192020.pdf

Location: <https://zoom.us/> (b) (6)

Start: 5/19/2020 1:00:00 PM

End: 5/19/2020 2:00:00 PM

Show Time As: Tentative

Recurrence: (none)

every Tuesday and Friday from 9:00 AM to 10:00 AM

Required Attendees: Vincent, Mike; Stein, Peter (FDA/CDER); Bascles, Lionel; Cohen, Myron; Corey, Larry; Desrosiers, Betsy; Dickens, Jim (NIH/NCATS) [C]; Doroshov, James (NIH/NCI) [E]; Goff, David (NIH/NHLBI) [E]; Kurilla, Mike; Nayak, Seema (NIH/NIAID) [E]; Parker, Ashley (NIH/OD) [E]; Payton, Manzine; Resnansky, Laura; Srinivasan, Badhri; Wachtel, Jonathan; Qashu, Felicia

Optional Attendees: Sizemore, Christine (NIH/FIC) [E]; Kenny, Dermot; Weinmann, Gail (NIH/NHLBI) [E]; Garner, Carlos; Colvis, Christine (NIH/NCATS) [E]; Hughes, Eric; Jansen, Kathrin; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Young, John; Adam, Stacey (FNIH) [T]; Anderson, Margaret; Carluccio, Dana; Cheryl (FNIH) Melencio [T] (b) (6); Francis Collins; Gonzalez, Nina; Heaton, Penny; James, Stephanie; Li, Rose; Menetski, Joseph (FNIH) [T]; Santos, Michael (FNIH); Tuveson, Nancy; Wholley, David (FNIH) [T]; Criffield, Robin; Hamilton, Nancy; Minnich, Beth; Rebecca (NIH/NCATS) Katz [E] (b) (6); Stratton, Benjamin; Tolman, Brett; Davey, Victoria; Jintanat Ananworanich

Dear Colleagues, We have an interesting agenda (attached) for this call and look forward to the discussion surrounding each topic! Best, Karen

ACTIV: Accelerating COVID-19 Therapeutic Interventions and Vaccines

Dear Clinical Trial Capacity Working Group members,

In anticipation of this working group making rapid progress on identified action items and other activities, the co-chairs have agreed that it will be important to hold twice-weekly calls to evaluate progress made by each subgroup, to identify areas of need, and to determine next steps. We ask that you make every effort possible to join each of these meetings, but understand that at times you may have competing priorities. To place a hold on your calendar, please accept this meeting invite with a response; later you can decline an individual meeting if you have a conflict.

An agenda and other meeting materials, as needed, will be distributed prior to each call.

With best regards,
Karen

Karen H. Tountas, PhD
Scientific Program Manager
Foundation for the National Institutes of Health

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From: Menetski, Joseph (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5001AF52DC4A427EA3D34F1E072F8CB7-MENETSKIJP]
Sent: 7/24/2020 5:25:36 PM
To: Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadbois@]
Subject: FW: Summary of the ACTIV Immune Modulator Prioritization Adjudication and Confidentiality Forms
Attachments: 2020-07-22_TX-Immune_Modulators_Summary.pdf; Therapeutic Clinical Working Group Confidentiality Agreement Individual Template 5-28-2020.docx; Therapeutic Clinical Working Group Confidentiality Agreement Institution Template 5-28-2020.docx

Ellen,

An example of what is going out when we need agreements to review therapeutics.

Joe

From: Adam, Stacey (FNIH) [T] < (b) (6) >
Sent: Friday, July 24, 2020 12:57 PM
To: Chen, Helen Q. < (b) (6) > (b) (6) Fessel, Josh (NIH/NHLBI) [E]
< (b) (6) > Deye, Greg (NIH/NIAID) [E] < (b) (6) > Punturieri, Antonello (NIH/NHLBI) [E]
< (b) (6) > McNamara, James (NIH/NIAID) [E] < (b) (6) > Wung, Peter /US
< (b) (6) > Vincent, Michael < (b) (6) > Goff, David (NIH/NHLBI) [E]
< (b) (6) > Garner, Carl < (b) (6) > Robien, Mark (NIH/NIAID) [E]
< (b) (6) > Toggias, Alkis (NIH/NIAID) [E] < (b) (6) > Patel, Naimish
< (b) (6) > Gottesdiener, Keith < (b) (6) > Eric Hughes
< (b) (6) > Aggarwal, Neil (NIH/NHLBI) [E] < (b) (6) > Levy, Elliot
< (b) (6) > Rosenberg, Yves (NIH/NHLBI) [E] < (b) (6) > Buchman, Tim (OS/ASPR/BARDA)
(CTR) < (b) (6) >
Cc: Dana Carluccio < (b) (6) > Rose Li Central Account < (b) (6) >
Read, Sarah (NIH/NIAID) [E] < (b) (6) > Young, John < (b) (6) > Colvis, Christine
(NIH/NCATS) [E] < (b) (6) > Menetski, Joseph (FNIH) [T] < (b) (6) > Alvarez, Rosa Maria
< (b) (6) >
Subject: Summary of the ACTIV Immune Modulator Prioritization Adjudication and Confidentiality Forms

Dear Agent Prioritization Immune Modulator Subteam,

Please find attached the summary of our adjudication meeting on Wednesday. If you have any additions or amendments, please let us know.

In addition, based on our last cycle of reviews, the group expressed a desire to request more information for a few compounds that are requesting CDAs to release the data. In order to obtain this information, we will need to sign a CDA with this group to receive the information. Therefore, we will also need each of you (who is not a government employee) to sign a confidentiality agreement with us, so that we can then share the data with you.

Please find attached the template for the confidentiality agreements that we have been using for any of our ACTIV TX-Clinical WG members that needed to view confidential information. You will see that there are two versions of the confidentiality agreement.

- One version is for those individuals who are able to sign this type of agreement on your own behalf.
- One version is for those individuals whose institutions require that the institutional signatory sign on the individual's behalf.

We provide both options upfront as we may not which will apply to each of you.

Please review the confidentiality agreement and send back the signed copy as soon as you can. Once we have all of these signed and the information from the agent teams, we will circulate to the group for final review and decision on that agent. Please note, if you signed one of these for the Antiviral group, it will apply this one as well and you do not need to sign another.

Please return your signed agreement to Helen or myself as soon as you can. If you have any questions, do not hesitate to reach out.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
Foundation for the National Institutes of Health
Direct: (b) (6) | Mobile: (b) (6)
fnih.org
11400 Rockville Pike, Suite 600, North Bethesda, MD 20852



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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 12/16/2020 4:11:56 PM
To: Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Draghia-Akli, Ruxandra [(b) (6) Eisner, Mark [(b) (6) Gottesdiener, Keith (b) (6) Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Kim, Elizabeth [(b) (6) LaVange, Lisa [(b) (6) Levy, Elliot [(b) (6) Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Menon, Sandeep [(b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Patel, Naimish (b) (6) Peppercorn, Amanda [(b) (6) Poole, Mike [(b) (6) Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Collins, Sylvia (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylvia.Collis]; Amanda Peppercorn [(b) (6) Garner, Carl (b) (6) Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Timothy Burgess [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=52e5e03dcbc847709eaab64457efa57e-TimothyBurg]; Reineck, Lora (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a62d88ba0c3b44e3bb922236c61304b3-reineckla]; Aggarwal, Neil (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c9de6615504ff9889f3b0c44a63526-aggarwalnr]; Rosenberg, Yves (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a5cb3e9a3a2747c38c42f68f5c8e40cf-roosenbey]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Brown, Jeremy (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce971eefec944a68a94add3b24835f5-brownj7]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Jacqueline Kirchner [(b) (6) Beigel, John (NIH) [E] [/o=ExchangeLabs/ou=Exchange Administrative

Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=492ae062f7d74e3cbd894e30160869f0-jbeigel]; Phillips, L Revell CIV DTRA RD (USA) [(b) (6) Petrovick, Martha - 0449 - MITLL [(b) (6) (b) (6) Sizemore, Christine (NIH/FIC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=05494833e0fc47a9acac194cd338b201-csizemore]

CC: Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Jansen, Kathrin [(b) (6) Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Young, John [(b) (6) Biggs, Mary [(b) (6) Butcher, Tina [(b) (6) Demarcus [(b) (6) Macone, Erin [(b) (6) Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Salathin, Carla [(b) (6) Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Dana Carluccio [(b) (6) Rose Li Central Account [(b) (6) Lucas Smalldon [(b) (6) Mollica, Linda /US [(b) (6) Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Marston, Hilary (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab30660917b942ffba9ae95d631116f3-marstonhd]; Chen, Helen Q. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user34aa917e]; Wung, Peter /US [(b) (6) Hoots, W. Keith (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=328221d5416d4fc59262c6c2eca59d4c-hootswk]; Groesch, Mary (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=69ab77a4c9bf499383186b9d9870344e-groeschm]; Shipp, Allan (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=16001e8ab49c4489aef107bd0ce27715-shippa]; Kindzelski, Andrei (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8bda5194bdca4d2594626f6313d2db5c-kindzelskia]; Hone, David M (Dave) CIV DTRA J9 (USA) [(b) (6) Reisler, Ronald B CTR USARMY DOD JPEO CBRND (USA) [(b) (6) Walker, Paula (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fbe81b9b832e40acb5fd03bafd32930-walkerp1]; Sorosa, Alex David [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userffc6da86]; Lumsden, Joanne (NIH/NCATS) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1be900c2388d41f48e3f2cbcb2fed349-lumsdenjm]

Subject: ACTIV Therapeutics-Clinical Working Group

Location: <https://fnih.zoom.us/> (b) (6)

Start: 1/7/2021 6:00:00 PM

End: 1/7/2021 7:00:00 PM

Show Time As: Tentative

Recurrence: Weekly
every Thursday from 1:00 PM to 2:00 PM

Required Attendees: Bozzette, Sam (NIH/NCATS) [E]; Butterson, Joan; De Claro, R. Angelo (FDA/CDER); Draghia-Akli, Ruxandra; Eisner, Mark; Gottesdiener, Keith; Hughes, Eric; Judy Currier; Kim, Elizabeth; LaVange, Lisa; Levy, Elliot; Mellors, John; Menon, Sandeep; Parker, Ashley (NIH/OD) [E]; Patel, Naimish; Peppercorn, Amanda; Poole, Mike; Proschan, Michael; Read, Sarah; Santos, Michael (FNIH) [T]; Shen, Yuan Li (FDA/CDER); Stein, Peter (FDA/CDER); Wholley, David (FNIH) [T]; Buchman, Tim (OS/ASPR/BARDA) (CTR); Collins, Sylva (FDA/CDER); Amanda Peppercorn; Garner, Carl; Higgs, Elizabeth (NIH/NIAID) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Timothy Burgess; Reineck, Lora (NIH/NHLBI) [E]; Aggarwal, Neil (NIH/NHLBI) [E]; Rosenberg, Yves (NIH/NHLBI) [E]; Goff, David (NIH/NHLBI) [E] (b) (6) Brown, Jeremy (NIH/NINDS) [E]; Gadbois, Ellen (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]; Jacqueline Kirchner;

Optional Attendees:

Colvis, Christine (NIH/NCATS) [E]; Jansen, Kathrin; Lowy, Douglas (NCI); Young, John; Biggs, Mary; Butcher, Tina; Demarcus; Macone, Erin; Melencio, Cheryl (FNIH) [T]; Salathin, Carla; Menetski, Joseph (FNIH) [T]; Dana Carluccio; Rose Li Central Account; Lucas Smalldon; (b) (6) Mollica, Linda /US; Qashu, Felicia (NIH/OD) [E]; Patterson, Amy (NIH/NHLBI) [E]; Rubin, Daniel B. (FDA/CDER); Marston, Hilary (NIH/NIAID) [E]; Chen, Helen Q.; Wung, Peter /US; Hoots, W. Keith (NIH/NHLBI) [E]; Groesch, Mary (NIH/NHLBI) [E]; Shipp, Allan (NIH/NHLBI) [E]; Kindzelski, Andrei (NIH/NHLBI) [E]; Hone, David M (Dave) CIV DTRA J9 (USA); Reisler, Ronald B CTR USARMY DOD JPEO CBRND (USA); Walker, Paula (NIH/NINDS) [E]; Sorosa, Alex David; Lumsden, Joanne (NIH/NCATS) [C]

Find your local number: <https://fnih.zoom.us>, (b) (6)

From: Brodd, Lauren (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=BA665DEA08E54171B3D6890C2518DDB9-LEPONELM]
Sent: 7/22/2020 5:59:50 PM
To: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]
Subject: RE: Summary of Communications Rollout plan for ACTIV clinical trials

Thanks for sharing!

Lauren

From: Parker, Ashley (NIH/OD) [E] <(b) (6)>
Sent: Wednesday, July 22, 2020 1:56 PM
To: Brodd, Lauren (NIH/OD) [E] <(b) (6)>
Subject: FW: Summary of Communications Rollout plan for ACTIV clinical trials

FYI

From: Melencio, Cheryl (FNIH) [T] (b) (6) > On Behalf Of Wholley, David (FNIH) [T]
Sent: Wednesday, July 22, 2020 1:50 PM
To: Austin, Christopher (NIH/NCATS) [E] <(b) (6)>; Bancel, Stephane
(b) (6) Carter, Kara (b) (6) >; Cavaleri, Marco
<(b) (6)>; Cihlar, Tomas (b) (6) >; Collins, Francis (NIH/OD) [E]
(b) (6) >; Corey, Larry (b) (6) >; Culp, Michelle (NIH/OD) [E] (b) (6) >;
Disbrow, Gary (OS/ASPR/BARDA) (b) (6) >; Dolsten, Mikael <(b) (6)>; Erbeling,
Emily (NIH/NIAID) [E] (b) (6) >; Erck, Stan (b) (6) >; Fauci, Anthony (NIH/NIAID) [E]
(b) (6) >; Freire, Maria (FNIH) [T] (b) (6) >; Gadbois, Ellen (NIH/OD) [E]
>; Gibbons, Gary (NIH/NHLBI) [E] (b) (6) >; Hudson, Thomas
(b) (6) >; James, Stephanie (FNIH) [T] (b) (6) >; Johnson, Robert (OS/ASPR/BARDA)
<(b) (6)>; Kramer, Lynn (b) (6) >; Lane, Cliff (NIH/NIAID) [E] (b) (6)
Lepore, John (b) (6) >; Marks, Peter (FDA/CBER) (b) (6) >; Marston, Hilary
(NIH/NIAID) [E] <(b) (6)>; Mascola, John (NIH/VRC) [E] (b) (6) >; Meeker, David
<(b) (6)>; Menetski, Joseph (FNIH) [T] (b) (6) >; Messonnier, Nancy (CDC/DDID/NCIRD/OD)
(b) (6) >; Pandya, Hitesh <(b) (6)>; Pangalos, Mene
<(b) (6)>
(b) (6) >; Paul, Steve (b) (6) >; Perlmutter, Roger (b) (6)
Plenge, Robert <(b) (6)>; Plump, Andy (b) (6) >; Rachel Ramoni
<(b) (6)>; Rasi, Guido <(b) (6)>; Reed, John <(b) (6)>; Reese, David
(b) (6) >; Rouse, Doris (b) (6) >; Santos, Michael (FNIH) [T] (b) (6) >; Skovronsky,
Daniel (b) (6) >; Stein, Peter (FDA/CDER) <(b) (6)>; Stoffels, Paul
<(b) (6)>; Tabak, Lawrence (NIH/OD) [E] <(b) (6)>; Talley, Michael
(b) (6) >; Tsai, John (b) (6) >; Vessey, Rupert (b) (6) >; Virgin, Skip
(b) (6) >; Wholley, David (FNIH) [T] (b) (6) >; Woodcock, Janet (FDA/CDER)
(b) (6) >; Young, John (b) (6) >; Colvis, Christine (NIH/NCATS) [E]
(b) (6) >; Desrosiers, Betsy (b) (6) >; Eric Hughes
(b) (6) >; Jansen, Kathrin (b) (6) >; Kurilla, Michael (NIH/NCATS) [E]
(b) (6) >; Lowy, Douglas (NCI) (b) (6) >; Read, Sarah (NIH/NIAID) [E] (b) (6)
Young, John <(b) (6)>
Cc: Anderson, James (NIH/OD) [E] (b) (6) >; Burklow, John (NIH/OD) [E] (b) (6)
Castillejos, Carlos (b) (6) >; Hallett, Adrienne (NIH/OD) [E] (b) (6) >; Myles, Renate
(NIH/OD) [E] <(b) (6)>; Wolinetz, Carrie (NIH/OD) [E] (b) (6) >; Adam, Stacey (FNIH) [T]

(b) (6) >; Alvarez, Rosa < (b) (6) : Anderson, Margaret (b) (6)
Chen, Helen < (b) (6) : Elsaid, Olivia (b) (6) : Gonzalez, Nina
(b) (6) >; James, Stephanie (FNIH) [T] (b) (6) ; Menetski, Joseph (FNIH) [T]
(b) (6) >; Santos, Michael (FNIH) [T] < (b) (6) : Stratton, Ben (b) (6) >;
Tolman, Brett (b) (6) : Tountas, Karen (FNIH) [T] (b) (6) >; Wachtel, Jonathan
< (b) (6) : Wholley, David (FNIH) [T] (b) (6) >; Meltzer, Abbey (FNIH) [T]
(b) (6) : Gorman, Greta (FNIH) [T] (b) (6)

Subject: Summary of Communications Rollout plan for ACTIV clinical trials

Dear Leadership Team members and associated staff:

As noted on our last Leadership Team call we are planning to begin launching shortly a series of master protocols designed or otherwise supported through ACTIV to test therapeutics and vaccines for COVID-19. Attached is the current draft summary of the communications plan for all of these activities. As noted, it will consist initially of a "treatment page" on the NIH ACTIV website that will provide an updated on ACTIV's progress and a general preview of the protocols that are planned, which will then be followed by a rollout of individual specific press releases and other media on each master protocol as it actually launches.

Although the NIH Communications team is working with the individual companies whose drugs are being tested to review detailed materials as they are created, they will not have time or resources to seek detailed feedback on the wording of press materials from every partner involved in ACTIV. However, you may share this summary with your organization's communications staff and they may contact Renate Myles (b) (6) at NIH if they have any questions.

We look forward to what should be a very exciting month for ACTIV!

Regards,
David Wholley

David Wholley
Senior Vice-President, Research Partnerships
Foundation for the National Institutes of Health
(b) (6)
fnih.org
11400 Rockville Pike Suite 600 North Bethesda, MD 20852

In 2019, the FNIH earned the highest rating from Charity Navigator for the fifth consecutive year and was recognized as an organization that exceeds industry standards.

From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 4/15/2020 7:24:02 PM
To: Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; Collins, Sylvia (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylvia.Colli]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Mark Eisner [(b) (6) Keith Gottesdiener [(b) (6) Eric Hughes [(b) (6) LaVange, Lisa M [(b) (6) Elliott Levy [(b) (6) Sandeep Menon [(b) (6) Amanda Peppercorn [(b) (6) Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Amanda Peppercorn [(b) (6) Price, Dionne (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a583eced842c44b18bb6fcd3820bee21-priced.fda]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]
CC: Mary Biggs [(b) (6) Demarcus [(b) (6) Macone, Erin [(b) (6) Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [(b) (6) Elizabeth Kim [(b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Rose Li Central Account [(b) (6) Lucas Smalldon [(b) (6) Butcher, Tina [(b) (6) Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]
Subject: Quick Response Needed to Poll for ACTIV TX-Clinical WG Master Protocol Subgroup -1st Meeting

Dear ACTIV Therapeutics-Clinical WG Master Protocol Subgroup Members,

I am sorry to have you fill out another availability poll, but per the conversation on the call, we want to see if enough people would be able to join a second call tomorrow at 11am US ET ahead of our large WG call. Please response to the Doodle poll below with your availability:

<https://doodle.com/poll/6ixkkekquxpd6sx>

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships

Direct: (b) (6) | Mobile: (b) (6)

APAR0000023425-2515810

From: Adam, Stacey (FNIH) [T]
Sent: Wednesday, April 15, 2020 12:33 PM
Subject: Materials for the ACTIV TX-Clinical WG Master Protocol Subgroup -1st Meeting
Importance: High

Dear ACTIV Therapeutics-Clinical WG Master Protocol Subgroup Members,

Thank you for joining the Master Protocol sub-group.

Our first meeting will take place today, **Wednesday April 15th from 1:30pm-2:30pm ET**. Dial-in instructions are below. Please find attached the materials for the meeting:

1. Agenda
2. Slides for the Presentation
3. PDFs of either the protocols or relevant publications for the trials that we are comparing in the landscape that seemed to be the most relevant. The only one missing is ACCORD as they are still finalizing and will send when done.
4. A Landscape Review of Master Protocols conducted in 2019
5. FDA Guidance on Master Protocols

Kind regards,
Stacey, on behalf of the ACTIV TX-Clinical WG

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
Direct: (b) (6) | Mobile: (b) (6)

Join Zoom Meeting

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US (San Jose)

US (San Jose)

US

US

Meeting ID: (b) (6)

Password: (b) (6)

Find your local number: <https://zoom.us>, (b) (6)

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 12/16/2020 2:40:23 PM
To: Brodd, Lauren (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ba665dea08e54171b3d6890c2518ddb9-leponelm]
Subject: FW: ACTIV Leadership Team Meeting, Tomorrow, December 16, 2020 -- CORRECTION
Attachments: 12.16 ACTIV EC and Leadership Team Meeting 20201215_vF (003).pdf; 12.16 ACTIV EC and Leadership Team Meeting_APPENDIX_20201215_vF.pdf; 2020-11-19_ACTIV_Leadership_Team_Meeting_Summary_v3.pdf

FYI

From: Melencio, Cheryl (FNIH) [T] < (b) (6) > **On Behalf Of** Wholley, David (FNIH) [T]
Sent: Tuesday, December 15, 2020 6:29 PM
To: Wholley, David (FNIH) [T] < (b) (6) > Austin, Christopher (NIH/NCATS) [E] < (b) (6) >
Bancel, Stephane < (b) (6) > Carter, Kara < (b) (6) > Cavaleri, Marco < (b) (6) >
Cihlar, Tomas < (b) (6) > Collins, Francis (NIH/OD) [E] < (b) (6) >
Corey, Larry < (b) (6) > Culp, Michelle (NIH/OD) [E] < (b) (6) >
Victoria Davey < (b) (6) > Disbrow, Gary (OS/ASPR/BARDA) < (b) (6) > Dolsten, Mikael < (b) (6) >
Erbelding, Emily (NIH/NIAID) [E] < (b) (6) > Erck, Stan < (b) (6) >
Fauci, Anthony (NIH/NIAID) [E] < (b) (6) > Freire, Maria (FNIH) [T] < (b) (6) >
Gadbois, Ellen (NIH/OD) [E] < (b) (6) > Gibbons, Gary (NIH/NHLBI) [E] < (b) (6) >
Hudson, Thomas < (b) (6) > James, Stephanie (FNIH) [T] < (b) (6) >
Johnson, Robert (OS/ASPR/BARDA) < (b) (6) > Kramer, Lynn < (b) (6) >
Lane, Cliff (NIH/NIAID) [E] < (b) (6) > Lepore, John < (b) (6) >
Marks, Peter (FDA/CBER) < (b) (6) > Marston, Hilary (NIH/NIAID) [E] < (b) (6) >
Mascola, John (NIH/VRC) [E] < (b) (6) > Meeker, David < (b) (6) > Menetski, Joseph (FNIH) [T] < (b) (6) >
Messonnier, Nancy (CDC/DDID/NCIRD/OD) < (b) (6) > Pandya, Hitesh < (b) (6) >
Pangalos, Mene < (b) (6) > Pao, William < (b) (6) >
Parker, Ashley (NIH/OD) [E] < (b) (6) > Paul, Steve < (b) (6) >
Perlmutter, Roger < (b) (6) > Plenge, Robert < (b) (6) > Plump, Andy < (b) (6) >
Rachel Ramoni < (b) (6) > Reed, John < (b) (6) > Reese, David < (b) (6) >
Rouse, Doris < (b) (6) > Santos, Michael (FNIH) [T] < (b) (6) >
Skovronsky, Daniel < (b) (6) > Stein, Peter (FDA/CDER) < (b) (6) > Stoffels, Paul < (b) (6) >
Tabak, Lawrence (NIH/OD) [E] < (b) (6) > Talley, Michael < (b) (6) >
Tsay, John < (b) (6) > Vessey, Rupert < (b) (6) > Virgin, Skip < (b) (6) >
Woodcock, Janet (FDA/CDER) < (b) (6) > Young, John < (b) (6) >
Colvis, Christine (NIH/NCATS) [E] < (b) (6) > Desrosiers, Betsy < (b) (6) >
Eric Hughes < (b) (6) > Jansen, Kathrin < (b) (6) >
Kurilla, Michael (NIH/NCATS) [E] < (b) (6) > Lowy, Douglas (NCI) < (b) (6) >
Read, Sarah (NIH/NIAID) [E] < (b) (6) > Young, John < (b) (6) >
Adam, Stacey (FNIH) [T] < (b) (6) > Margaret Anderson < (b) (6) > Appell, Evan < (b) (6) >
Chen, Helen Q. < (b) (6) > Connelly, Sarah < (b) (6) >
Gonzalez, Nina < (b) (6) > Hawk, Harrison < (b) (6) > Mendelson, Jesse < (b) (6) >
Menetski, Joseph (FNIH) [T] < (b) (6) > Nasr, Hana < (b) (6) >
Santos, Michael (FNIH) [T] < (b) (6) > Sorosa, Alex David < (b) (6) > Stratton, Benjamin < (b) (6) >
btolman < (b) (6) > Tountas, Karen (FNIH) [T] < (b) (6) >
Wachtel, Jonathan < (b) (6) >
Cc: Anderson, James (NIH/OD) [E] < (b) (6) > Austin, Christopher (NIH/NCATS) [E] < (b) (6) >
Burklow, John (NIH/OD) [E] < (b) (6) > Carluccio, Dana < (b) (6) >
Castillejos, Carlos < (b) (6) > FNIH Central Account < (b) (6) >
Hallett, Adrienne (NIH/OD) [E] < (b) (6) > Lane, Cliff (NIH/NIAID) [E] < (b) (6) >
Myles, Renate (NIH/OD) [E] < (b) (6) > Parker, Ashley (NIH/OD) [E] < (b) (6) >

< (b) (6) Tabak, Lawrence (NIH/OD) [E] < (b) (6) Wolinetz, Carrie (NIH/OD) [E]

< (b) (6) Meltzer, Abbey (FNIH) [T] < (b) (6)

Subject: RE: ACTIV Leadership Team Meeting, Tomorrow, December 16, 2020 -- CORRECTION

Dear ACTIV Leadership Team and meeting attendees:

Please see corrected version of materials. Sorry for the confusion.

Regards,

David

David Wholley
Senior Vice-President, Research Partnerships
Foundation for the National Institutes of Health

(b) (6)

fnih.org

11400 Rockville Pike Suite 600 North Bethesda, MD 20852

In 2019, the FNIH earned the highest rating from Charity Navigator for the fifth consecutive year and was recognized as an organization that exceeds industry standards.

From: Melencio, Cheryl (FNIH) [T] < (b) (6) > **On Behalf Of** Wholley, David (FNIH) [T]

Sent: Tuesday, December 15, 2020 5:08 PM

To: Austin, Christopher (NIH/NCATS) [E] < (b) (6) >; Bancel, Stephane

< (b) (6) >; Carter, Kara < (b) (6) >; Cavaleri, Marco

<marco.cavaleri@ema.europa.eu>; Cihlar, Tomas < (b) (6) >; Collins, Francis (NIH/OD) [E]

< (b) (6) >; Corey, Larry < (b) (6) >; Culp, Michelle (NIH/OD) [E] < (b) (6) >

Victoria Davey < (b) (6) >; Disbrow, Gary (OS/ASPR/BARDA) < (b) (6) >; Dolsten, Mikael

< (b) (6) >; Erbelding, Emily (NIH/NIAID) [E] < (b) (6) >; Erck, Stan

< (b) (6) >; Fauci, Anthony (NIH/NIAID) [E] < (b) (6) >; Freire, Maria (FNIH) [T]

< (b) (6) >; Gadbois, Ellen (NIH/OD) [E] < (b) (6) >; Gibbons, Gary (NIH/NHLBI) [E]

< (b) (6) >; Hudson, Thomas < (b) (6) >; James, Stephanie (FNIH) [T]

< (b) (6) >; Johnson, Robert (OS/ASPR/BARDA) < (b) (6) >; Kramer, Lynn

< (b) (6) >; Lane, Cliff (NIH/NIAID) [E] < (b) (6) >; Lepore, John < (b) (6) >

Marks, Peter (FDA/CBER) < (b) (6) >; Marston, Hilary (NIH/NIAID) [E] < (b) (6) >

Mascola, John (NIH/VRC) [E] < (b) (6) >; Meeker, David < (b) (6) >; Menetski, Joseph

(FNIH) [T] < (b) (6) >; Messonnier, Nancy (CDC/DDID/NCIRD/OD) < (b) (6) >; Pandya, Hitesh

< (b) (6) >; Pangalos, Mene < (b) (6) >; Pao, William

< (b) (6) >; Parker, Ashley (NIH/OD) [E] < (b) (6) >; Paul, Steve < (b) (6) >

Perlmutter, Roger < (b) (6) >; Plenge, Robert < (b) (6) >; Plump, Andy

< (b) (6) >; Rachel Ramoni < (b) (6) >; Reed, John < (b) (6) >; Reese,

David < (b) (6) >; Rouse, Doris < (b) (6) >; Santos, Michael (FNIH) [T] < (b) (6) >

Skovronsky, Daniel < (b) (6) >; Stein, Peter (FDA/CDER) < (b) (6) >; Stoffels, Paul

< (b) (6) >; Tabak, Lawrence (NIH/OD) [E] < (b) (6) >; Talley, Michael

< (b) (6) >; Tsai, John < (b) (6) >; Vessey, Rupert < (b) (6) >; Virgin, Skip

< (b) (6) >; Wholley, David (FNIH) [T] < (b) (6) >; Woodcock, Janet (FDA/CDER)

< (b) (6) >; Young, John < (b) (6) >; Colvis, Christine (NIH/NCATS) [E]

< (b) (6) >; Desrosiers, Betsy < (b) (6) >; Eric Hughes

< (b) (6) >; Jansen, Kathrin < (b) (6) >; Kurilla, Michael (NIH/NCATS) [E]

(b) (6) ; Lowy, Douglas (NCI) < (b) (6) Read, Sarah (NIH/NIAID) [E] < (b) (6)
Young, John (b) (6) >; Adam, Stacey (FNIH) [T] (b) (6) >; Margaret Anderson
(b) (6) m>; Appell, Evan (b) (6) >; Chen, Helen Q. (b) (6) >;
Connelly, Sarah < (b) (6) ; Gonzalez, Nina (b) (6) >; Hawk, Harrison
(b) (6) >; Mendelson, Jesse (b) (6) >; Menetski, Joseph (FNIH) [T]
(b) (6) >; Nasr, Hana (b) (6) >; Santos, Michael (FNIH) [T] (b) (6) ; Sorosa,
Alex David (b) (6) >; Stratton, Benjamin (b) (6) >; btolman (b) (6) >;
Tountas, Karen (FNIH) [T] (b) (6) ; Wachtel, Jonathan (b) (6) >; Wholley, David (FNIH) [T]
(b) (6) >
Cc: Anderson, James (NIH/OD) [E] (b) (6) >; Austin, Christopher (NIH/NCATS) [E]
< (b) (6) ; Burklow, John (NIH/OD) [E] (b) (6) >; Carluccio, Dana
(b) (6) >; Castillejos, Carlos < (b) (6) >; FNIH Central Account
(b) (6) ; Hallett, Adrienne (NIH/OD) [E] (b) (6) >; Lane, Cliff (NIH/NIAID) [E]
(b) (6) >; Myles, Renate (NIH/OD) [E] (b) (6) ; Parker, Ashley (NIH/OD) [E]
(b) (6) ; Tabak, Lawrence (NIH/OD) [E] < (b) (6) ; Wolinetz, Carrie (NIH/OD) [E]
(b) (6) >; Meltzer, Abbey (FNIH) [T] < (
Subject: ACTIV Leadership Team Meeting, Tomorrow, December 16, 2020

Dear ACTIV Leadership Team and meeting attendees:

Attached please find the slides for our meeting **tomorrow, Wednesday, December 16, 10:00 – 11:30 a.m. Eastern U.S. Time**. The minutes from the November 19 Leadership Team call are attached to this note.

The logistics for the Zoom call, which were previously sent to you in the Outlook calendar invitation, are as follows:

Join Zoom Meeting

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(b) (6) US (Tacoma)
(b) (6) US (Houston)

Belgium
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Meeting ID: (b) (6)

Passcode: (b) (6)

Find your local number: <https://fnih.zoom.us> (b) (6)

Please let Joe Menetski or Cheryl Melencio here at FNIH (copied) know if you are having any problems connecting. I look forward to a productive meeting.

Regards,

David

David Wholley

Senior Vice-President, Research Partnerships

Foundation for the National Institutes of Health

(b) (6)

fnih.org

11400 Rockville Pike Suite 600 North Bethesda, MD 20852

In 2019, the FNIH earned the highest rating from Charity Navigator for the fifth consecutive year and was recognized as an organization that exceeds industry standards.

From: Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415BB86087D08B628E6F-MELENCIOC]
on behalf of Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 2/17/2021 12:03:01 AM
To: Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Bancel, Stephane [(b) (6) Carter, Kara [(b) (6) Cavaleri, Marco [(b) (6) Cihlar, Tomas [(b) (6) Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Corey, Larry [(b) (6) Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Victoria Davey [(b) (6) Disbrow, Gary (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c8291f38ec342f895243c0617e115ec-victoria.da]; Dolsten, Mikael [(b) (6) Embry, Alan (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=882a18a10a134c49acac21cb83fd599d-embrya]; Erbeling, Emily (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e976ebf7b14142fbb3c5c294efb334fe-erbelingej]; Erck, Stan [(b) (6) Fauci, Anthony (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=df38103d75134f658ae2d356f0396b94-afauci]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freirem]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Gibbons, Gary (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b71b953b50a5495ca0f2869ab13bc407-gibbonsgh]; Hudson, Thomas [(b) (6) James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Johnson, Robert (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=feb0b05457404e2f8b88af78e9ac4dd9-Robert.John]; Kramer, Lynn [(b) (6) Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Lepore, John [(b) (6) Marks, Peter (FDA/CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b2e527bdba2b4a86b8d72f06b813d471-MarksP.fda]; Mascola, John (NIH/VRC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f78b40a596b4ca4a2850a429d1ae3f2-jmascola]; Meeker, David [(b) (6) Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Messonnier, Nancy (CDC/DDID/NCIRD/OD) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=441f65db836c4a89a42aecb9a0d9b96c-NAR5]; Pandya, Hitesh [(b) (6) Pangalos, Mene [(b) (6) Pao, William [(b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Paul, Steve [(b) (6) Perlmutter, Roger [(b) (6) Plenge, Robert [(b) (6) Plump, Andy [(b) (6) Rachel Ramoni [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d3f6cb5237a44b75887b8a1ca1f9bb91-Rachel.Ramo]; Reed, John [(b) (6) Reese, David [(b) (6) Rouse, Doris [(b) (6) Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Skovronsky, Daniel [(b) (6) Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Stoffels, Paul [(b) (6) Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Talley, Michael [(b) (6) Tsai, John [(b) (6) Vessey, Rupert [(b) (6)]; Virgin,

Skip [(b) (6) Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Woodcock, Janet (FDA/OC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebfcf48879f92169bd7644e29-Janet.Woodc]; Young, John [(b) (6) Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy [(b) (6) Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Jansen, Kathrin [(b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Young, John

CC: [(b) (6) Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Burklow, John (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e57f267323b43c08be856acb5b964ca-burklowj]; Carluccio, Dana [(b) (6) Castillejos, Carlos [(b) (6) Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; FNIH Central Account [(b) (6) Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Hallett, Adrienne (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1705e2e7c254b84a77f058dbf75b31b-hallettaa]; Lumsden, Joanne (NIH/NCATS) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1be900c2388d41f48e3f2cbcb2fed349-lumsdenjm]; Myles, Renate (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d317f5626934585b3692a1823c1b522-mylesr]; Wolinetz, Carrie (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1c655040d47346c7b04d7bc11a403ecb-wolinetzcd]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Margaret Anderson [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab9a138f1e284c689fedfb10b8cc5295-marganderso]; Appell, Evan [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user7ee69e83]; Chen, Helen [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8801b022ef974bf7bda8fd06f67002cf-qingchen.de]; Connelly, Sarah [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3ed93bab]; Dally, Nicole [(b) (6) Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Hawk, Harrison [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user280c84f8]; Mendelson, Jesse [(b) (6) Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Nasr, Hana [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userfe0939a1]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Sorosa, Alex [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a221a6336336466793cff9145b09d91b-Contact_f12]; Stratton, Benjamin [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=usere3ed7188]; Tolman, Brett [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user7b137a1e]; Wachtel, Jonathan [(b) (6) Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Burklow, John (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e57f267323b43c08be856acb5b964ca-burklowj]; Hallett, Adrienne (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

Subject: ACTIV Joint Executive Committee & Leadership Team Meeting; tomorrow, February 17, 2021
Attachments: 02.17.21 ACTIV EC and Leadership Team Meeting 20210216_vF.pdf; 02.17.21 ACTIV EC and Leadership Team Meeting_APPENDIX_20210216_vF.pdf; 2021-01-14_ACTIV_Leadership_Team_and_Executive_Committee_Meeting_Summary_vF.pdf

Attached please find the slides for our meeting **tomorrow, Wednesday, February 17, from 11:30 a.m. to 1:00 p.m. Eastern U.S. Time.** The minutes from the January 14 Executive Committee/Leadership Team call are also attached to this note.

<https://fnih.zoom.us/> (b) (6)

(b) (6) JS (Washington D.C.)
JS (Chicago)

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Meeting ID: (b) (6)

Passcode: (b) (6)

Find your local number: <https://fnih.zoom.us> (b) (6)

Please let Joe Menetski or Cheryl Melencio here at FNIH (copied) know if you are having any problems connecting. I look forward to a productive meeting.

Regards,

David

David Wholley
Senior Vice-President, Research Partnerships
Foundation for the National Institutes of Health

(b) (6)

fnih.org

11400 Rockville Pike Suite 600 North Bethesda, MD 20852

In 2019, the FNIH earned the highest rating from Charity Navigator for the fifth consecutive year and was recognized as an organization that exceeds industry standards.

From: Prabha Fernandes (b) (6)
Sent: 1/14/2021 8:33:13 PM
To: Fessel, Josh (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=294e2bb481d94b83a1917f15338dfe19-fesseljp]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; (b) (6) (b) (6) (b) (6) Hild, Sheri (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=edd7f1939fb94be3bf063f925ac15f02-hildsa]; (b) (6) m; (b) (6) (b) (6) (b) (6) Baric, Ralph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.email]; Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcb42cbb4014d9b26af30cc-jhewitt]; Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda]; (b) (6) (b) (6) (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; (b) (6) Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; 'Rao, Srinivas' [(b) (6) Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; 'Tomas Cihlar' [(b) (6) 'Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA)' [(b) (6) Punturieri, Antonello (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ca7f3106e5f24b5cb5e933c6ee7a6bc7-punturiera]; Charette, Marc (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7fa2baf951848b5bf1f76a049a0eca6-charettemf]; (b) (6)
CC: Hawk, Harrison [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user280c84f8]; caroline.sferrazza@roseliassociates.com; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; (b) (6) Florence, Clint (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; 'Desrosiers, Betsy' [(b) (6) Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; 'Jansen, Kathrin' [(b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Tountas, Karen (FNIH) [T]

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[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user706e5647]; 'Kim,
Elizabeth' [(b) (6) btolman [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=user7b137a1e]; 'Wachtel, Jonathan' (b) (6) 'Prabhavathi
Fernandes' [(b) (6) 'Diamond, Michael' [(b) (6) 'Rose Li'
(b) (6) 'Dana Carluccio' [(b) (6) Lagos, Enrique (NIH/NCATS)
[E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagoses]; Jonson, Samantha
(NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Burrus-Shaw, Cyndi
(NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; 'Rodriguez, Robin D'
[(b) (6) 'Dave Frankowski' [(b) (6) antoinette_baric
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userb6b844cf]; Lowy,
Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; Nancy Haigwood
[/o=ExchangeLabs/ou=Exchange Administrative Group
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[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=usere3ed7188];
Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Anderson, James
(NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; 'Mason, Stephen'
[(b) (6) Connelly, Sarah [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=user3ed93bab]; (b) (6) Lumsden, Joanne (NIH/NCATS) [C]
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=1be900c2388d41f48e3f2cbcb2fed349-lumsdenjm]; 'K C Kent Lloyd'
[(b) (6)

Subject: RE: ACTIV Preclinical full working group

Attachments: The Problem of 'Long Haul' COVID - Scientific American.pdf

Dear All,

The problem is getting good lay press. I got this from Scientific American!

Regards,

Prabha

From: Fessel, Josh (NIH/NHLBI) [E] < (b) (6) >

Sent: Wednesday, January 13, 2021 11:54 AM

To: Menetski, Joseph (FNIH) [T] < (b) (6) > (b) (6) (b) (6)

(b) (6) Hild, Sheri (NIH/OD) [E] < (b) (6) > (b) (6)

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(b) (6) Ottinger, Elizabeth (NIH/NCATS) [E] < (b) (6) > Colvis, Christine

(NIH/NCATS) [E] < (b) (6) > Hewitt, Judith (NIH/NIAID) [E] < (b) (6) > Deming, Damon

(FDA/CDER) < (b) (6) > (b) (6) (b) (6) (b) (6)

Parker, Ashley (NIH/OD) [E] < (b) (6) > Collins, Francis (NIH/OD) [E] < (b) (6) >

(b) (6) Adams, Peter (OS/ASPR/BARDA) < (b) (6) > Rao, Srinivas

< (b) (6) > Qashu, Felicia (NIH/OD) [E] < (b) (6) > Tomas Cihlar

< (b) (6) Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA) < (b) (6)
Punturieri, Antonello (NIH/NHLBI) [E] < (b) (6) Charette, Marc (NIH/NHLBI) [E]
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Cc: Hawk, Harrison < (b) (6) (b) (6) Gonzalez, Nina
< (b) (6) (b) (6) Florence, Clint (NIH/NIAID) [E] < (b) (6) Simon,
Dina (NIH/OD) [C] < (b) (6) Wholley, David (FNIH) [T] < (b) (6) Austin, Christopher
(NIH/NCATS) [E] < (b) (6) Melencio, Cheryl (FNIH) [T] < (b) (6) Colvis, Christine
(NIH/NCATS) [E] < (b) (6) Desrosiers, Betsy < (b) (6) Eric Hughes
< (b) (6) Jansen, Kathrin < (b) (6) Kurilla, Michael (NIH/NCATS) [E]
< (b) (6) Lowy, Douglas (NCI) < (b) (6) Read, Sarah (NIH/NIAID) [E] < (b) (6)
Tountas, Karen (FNIH) [T] < (b) (6) Santos, Michael (FNIH) [T] < (b) (6) Adam, Stacey (FNIH) [T]
< (b) (6) James, Stephanie (FNIH) [T] < (b) (6) Alvarez, Rosa Maria < (b) (6)
Kim, Elizabeth < (b) (6) btolman < (b) (6) Wachtel, Jonathan < (b) (6)
Prabhavathi Fernandes < (b) (6) Diamond, Michael < (b) (6) Rose Li
< (b) (6) Dana Carluccio < (b) (6) Lagos, Enrique (NIH/NCATS) [E]
< (b) (6) Jonson, Samantha (NIH/NCATS) [E] < (b) (6) Burrus-Shaw, Cyndi
(NIH/OD) [E] < (b) (6) Rodriguez, Robin D < (b) (6) Dave Frankowski
< (b) (6) antoinette_baric < (b) (6) Lowy, Douglas
(NIH/NCI) [E] < (b) (6) Nancy Haigwood < (b) (6) Stratton, Benjamin
< (b) (6) Gadbois, Ellen (NIH/OD) [E] < (b) (6) Anderson, James (NIH/OD) [E]
< (b) (6) Mason, Stephen < (b) (6) Connelly, Sarah
< (b) (6) (b) (6) Lumsden, Joanne (NIH/NCATS) [C] < (b) (6) K C Kent
Lloyd < (b) (6)

Subject: RE: ACTIV Preclinical full working group

Hi everyone,

Joe, thanks for sharing! This article is getting a lot of attention, and understandably so. There's a nice Commentary that accompanied it, and I'm attaching that as well. Prabha, thanks for sharing the article you shared as well!

The study like this one that's been on my mind is the attached preprint from medRxiv. It's a patient-led research effort (from the group that was in attendance at the recent trans-NIH workshop on Post-Acute Sequelae of COVID, hosted by NIAID), which I think some might see as a negative (consciously or unconsciously). For me, that's one of its chief strengths. Long COVID is at present a symptom-defined syndrome, and the patients are our best teachers. Though the study reported in the medRxiv manuscript is by no means perfect, I've found it to be very informative.

Thanks so much, everyone!

All my best,

Josh

Josh Fessel, MD, PhD

Pronouns: he/him/his

Medical Officer/Program Director – Vascular Biology & Pulmonary Hypertension

Division of Lung Diseases | National Heart, Lung, and Blood Institute

National Institutes of Health

6705 Rockledge Drive | Room 405-F, MSC 7952 | Bethesda, MD 20892-7952

Phone: (b) (6)

Mobile: (b) (6) (urgent/emergent use only, please)

Email: (b) (6)

From: Menetski, Joseph (FNIH) [T] (b) (6)

Sent: Wednesday, January 13, 2021 10:55 AM

To: (b) (6); Hild, Sheri (NIH/OD) [E]
(b) (6) Baric,
Ralph (b) (6) (b) (6); Ottinger, Elizabeth (NIH/NCATS) [E]
(b) (6) >; Colvis, Christine (NIH/NCATS) [E] (b) (6); Hewitt, Judith (NIH/NIAID)
[E] (b) (6) >; Deming, Damon (FDA/CDER) (b) (6)
(b) (6); Parker, Ashley (NIH/OD) [E] (b) (6) >; Collins, Francis
(NIH/OD) [E] (b) (6); Adams, Peter (OS/ASPR/BARDA)
(b) (6); Rao, Srinivas (b) (6) >; Qashu, Felicia (NIH/OD) [E]
(b) (6); Tomas Cihlar (b) (6); Pitt, Margaret L CIV USARMY MEDCOM USAMRIID
(USA) (b) (6); Punturieri, Antonello (NIH/NHLBI) [E] (b) (6); Charette, Marc
(NIH/NHLBI) [E] (b) (6) >; Fessel, Josh (NIH/NHLBI) [E] (b) (6);
(b) (6);

Cc: Hawk, Harrison (b) (6) Gonzalez, Nina
(b) (6) Florence, Clint (NIH/NIAID) [E] (b) (6) Simon,
Dina (NIH/OD) [C] <(b) (6)> Wholley, David (FNIH) [T] <(b) (6)> Austin, Christopher
(NIH/NCATS) [E] (b) (6); Melencio, Cheryl (FNIH) [T] (b) (6) >; Colvis, Christine
(NIH/NCATS) [E] (b) (6) >; Desrosiers, Betsy (b) (6) Eric Hughes
(b) (6); Jansen, Kathrin (b) (6); Kurilla, Michael (NIH/NCATS) [E]
(b) (6) >; Lowy, Douglas (NCI) (b) (6) >; Read, Sarah (NIH/NIAID) [E] <(b) (6)>
Tountas, Karen (FNIH) [T] (b) (6); Santos, Michael (FNIH) [T] (b) (6) >; Adam, Stacey (FNIH) [T]
(b) (6); James, Stephanie (FNIH) [T] (b) (6) >; Alvarez, Rosa Maria (b) (6)
Kim, Elizabeth (b) (6) >; btolman (b) (6) >; Wachtel, Jonathan <(b) (6)>
Prabhavathi Fernandes (b) (6) >; Diamond, Michael (b) (6) >; Rose Li
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(NIH/OD) [E] <cyndi.burrus- (b) (6)> Rodriguez, Robin D <(b) (6)> Dave Frankowski
(b) (6) antoinette_baric (b) (6) Lowy, Douglas
(NIH/NCI) [E] (b) (6); Nancy Haigwood <haigwood@ohsu.edu>; Stratton, Benjamin
<(b) (6)> Gadbois, Ellen (NIH/OD) [E] <(b) (6)> Anderson, James (NIH/OD) [E]
(b) (6) >; Mason, Stephen (b) (6) Connelly, Sarah
<(b) (6)> Lumsden, Joanne (NIH/NCATS) [C] (b) (6) K C Kent
Lloyd (b) (6) >

Subject: RE: ACTIV Preclinical full working group

Dear all,

Thought you might be interested in this article on COVID-19 sequalae.

Does anyone know of other reports like this? It could be important to incorporate this in our thoughts for therapeutics going forward.

Best regards,
Joe

From: Gadbois, Ellen (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0243D1D6E6F248268D2EDEC566C26C2A-GADBOISEL]
Sent: 12/18/2020 5:11:10 PM
To: Tucker, Jessica (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2baf4ae78d90412dbef0ffb5e52c31a4-tuckerjm]
Subject: RE: ACTIV slides from today on escape mutations

And more from the FNIH/Deloitte call—Moncef Slaoui is going to ask BARDA for the funds for this project. FNIH is prepping a budget.

From: Gadbois, Ellen (NIH/OD) [E]
Sent: Friday, December 18, 2020 10:41 AM
To: Tucker, Jessica (NIH/OD) [E] <(b) (6)>
Subject: RE: ACTIV slides from today on escape mutations

More today on the ACTIV preclinical WG call: FYI this whole effort also includes escape mutants from the vaccines, not just the therapeutics. And I think the member from Roche said something like there are already mutations known to affect efficacy of cocktails (presumably of antibodies), but I am not sure I heard that right. At any rate, I keep hearing the FDA is requiring companies to generate this information.

From: Tucker, Jessica (NIH/OD) [E] <(b) (6)>
Sent: Wednesday, December 16, 2020 4:17 PM
To: Gadbois, Ellen (NIH/OD) [E] <(b) (6)>
Subject: RE: ACTIV slides from today on escape mutations

Thank you!

From: Gadbois, Ellen (NIH/OD) [E] <(b) (6)>
Sent: Wednesday, December 16, 2020 1:16 PM
To: Tucker, Jessica (NIH/OD) [E] <(b) (6)>
Subject: FYI: ACTIV slides from today on escape mutations

See slides 6-10. Note that slide 8 includes “selection screens.” There was general enthusiasm on the call today for the general effort and FC asked industry members what they could do to help. Skip Virgin from VIR said that there are certain experiments that FDA is also asking sponsors to conduct and so centralizing assays and information was important. There was then discussion of a platform that FDA/BARDA/OWS has apparently already built that takes sequence data, makes pseudotype viruses, and run them against a panel of antibodies. (I had to look up pseudotyping—it sounds like it is making a replication incompetent virus.) Not much more detail.

From: Melencio, Cheryl (FNIH) [T] <(b) (6)> > On Behalf Of Wholley, David (FNIH) [T]
Sent: Tuesday, December 15, 2020 6:29 PM
To: Wholley, David (FNIH) [T] <(b) (6)>; Austin, Christopher (NIH/NCATS) [E] <(b) (6)>; Bancel, Stephane <(b) (6)>; Carter, Kara <(b) (6)>; Cavaleri, Marco <(b) (6)>; Cihlar, Tomas <(b) (6)>; Collins, Francis (NIH/OD) [E] <(b) (6)>; Corey, Larry <(b) (6)>; Culp, Michelle (NIH/OD) [E] <(b) (6)>; Victoria Davey <(b) (6)>; Disbrow, Gary (OS/ASPR/BARDA) <(b) (6)>; Dolsten, Mikael <(b) (6)>; Erbeling, Emily (NIH/NIAID) [E] <(b) (6)>; Erck, Stan <(b) (6)>; Fauci, Anthony (NIH/NIAID) [E] <(b) (6)>; Freire, Maria (FNIH) [T] <(b) (6)>; Gadbois, Ellen (NIH/OD) [E] <(b) (6)>; Gibbons, Gary (NIH/NHLBI) [E] <(b) (6)>; Hudson, Thomas <(b) (6)>; James, Stephanie (FNIH) [T]

< (b) (6) : Johnson, Robert (OS/ASPR/BARDA) (b) (6) ; Kramer, Lynn
 (b) (6) ; Lane, Cliff (NIH/NIAID) [E] (b) (6) ; Lepore, John (b) (6)
 Marks, Peter (FDA/CBER) < (b) (6) Marston, Hilary (NIH/NIAID) [E] < (b) (6) ;
 Mascola, John (NIH/VRC) [E] (b) (6) >; Meeker, David (b) (6) ; Menetski, Joseph
 (FNIH) [T] (b) (6) Messonnier, Nancy (CDC/DDID/NCIRD/OD) < (b) (6) Pandya, Hitesh
 (b) (6) >; Pangalos, Mene (b) (6) >; Pao, William
 < (b) (6) ; Parker, Ashley (NIH/OD) [E] (b) (6) >; Paul, Steve (b) (6)
 Perlmutter, Roger (b) (6) Plenge, Robert < (b) (6) Plump, Andy
 < (b) (6) ; Rachel Ramoni (b) (6) Reed, John (b) (6) >; Reese,
 David (b) (6) Rouse, Doris (b) (6) Santos, Michael (FNIH) [T] < (b) (6)
 Skovronsky, Daniel (b) (6) >; Stein, Peter (FDA/CDER) (b) (6) Stoffels, Paul
 < (b) (6) Tabak, Lawrence (NIH/OD) [E] (b) (6) >; Talley, Michael
 < (b) (6) Tsai, John (b) (6) >; Vessey, Rupert (b) (6) >; Virgin, Skip
 (b) (6) Woodcock, Janet (FDA/CDER) (b) (6) >; Young, John
 (b) (6) >; Colvis, Christine (NIH/NCATS) [E] (b) (6) Desrosiers, Betsy
 (b) (6) >; Eric Hughes (b) (6) >; Jansen, Kathrin
 (b) (6) Kurilla, Michael (NIH/NCATS) [E] < (b) (6) Lowy, Douglas (NCI)
 < (b) (6) Read, Sarah (NIH/NIAID) [E] < (b) (6) Young, John (b) (6) >;
 Adam, Stacey (FNIH) [T] (b) (6) Margaret Anderson < (b) (6) Appell, Evan
 (b) (6) >; Chen, Helen Q. < (b) (6) >; Connelly, Sarah (b) (6)
 Gonzalez, Nina (b) (6) Hawk, Harrison < (b) (6) Mendelson, Jesse
 (b) (6) >; Menetski, Joseph (FNIH) [T] (b) (6) Nasr, Hana (b) (6)
 Santos, Michael (FNIH) [T] (b) (6) >; Sorosa, Alex David < (b) (6) >; Stratton, Benjamin
 < (b) (6) btolman < (b) (6) >; Tountas, Karen (FNIH) [T] (b) (6)
 Wachtel, Jonathan (b) (6)
Cc: Anderson, James (NIH/OD) [E] (b) (6) Austin, Christopher (NIH/NCATS) [E]
 (b) (6) Burklow, John (NIH/OD) [E] (b) (6) >; Carluccio, Dana
 (b) (6) Castillejos, Carlos < (b) (6) >; FNIH Central Account
 (b) (6) >; Hallett, Adrienne (NIH/OD) [E] (b) (6) >; Lane, Cliff (NIH/NIAID) [E]
 (b) (6) ; Myles, Renate (NIH/OD) [E] < (b) (6) (Parker, Ashley (NIH/OD) [E]
) (b) (6) Tabak, Lawrence (NIH/OD) [E] (b) (6) Wolinetz, Carrie (NIH/OD) [E]
 (b) (6) ; Meltzer, Abbey (FNIH) [T] (b) (6)

Subject: RE: ACTIV Leadership Team Meeting, Tomorrow, December 16, 2020 -- CORRECTION

Dear ACTIV Leadership Team and meeting attendees:

Please see corrected version of materials. Sorry for the confusion.

Regards,

David

David Wholley
 Senior Vice-President, Research Partnerships
 Foundation for the National Institutes of Health
 (b) (6)

fnih.org
 11400 Rockville Pike Suite 600 North Bethesda, MD 20852

In 2019, the FNIH earned the highest rating from Charity Navigator for the fifth consecutive year and was recognized as an organization that exceeds industry standards.

From: Melencio, Cheryl (FNIH) [T] (b) (6) > **On Behalf Of** Wholley, David (FNIH) [T]
Sent: Tuesday, December 15, 2020 5:08 PM
To: Austin, Christopher (NIH/NCATS) [E] (b) (6) >; Bancel, Stephane
 (b) (6) >; Carter, Kara (b) (6) >; Cavaleri, Marco
 (b) (6) >; Cihlar, Tomas (b) (6) >; Collins, Francis (NIH/OD) [E]
 (b) (6) Corey, Larry < (b) (6) ; Culp, Michelle (NIH/OD) [E] (b) (6) >;
 Victoria Davey < (b) (6) ; Disbrow, Gary (OS/ASPR/BARDA) (b) (6) >; Dolsten, Mikael
 (b) (6) Erbelding, Emily (NIH/NIAID) [E] (b) (6) ; Erck, Stan
 < (b) (6) >; Fauci, Anthony (NIH/NIAID) [E] < (b) (6) Freire, Maria (FNIH) [T]
 < (b) (6) ; Gadbois, Ellen (NIH/OD) [E] (b) (6) ; Gibbons, Gary (NIH/NHLBI) [E]
 (b) (6) >; Hudson, Thomas (b) (6) >; James, Stephanie (FNIH) [T]
 (b) (6) >; Johnson, Robert (OS/ASPR/BARDA) (b) (6) >; Kramer, Lynn
 (b) (6) Lane, Cliff (NIH/NIAID) [E] (b) (6) Lepore, John < (b) (6)
 Marks, Peter (FDA/CBER) < (b) (6) >; Marston, Hilary (NIH/NIAID) [E] (b) (6) ;
 Mascola, John (NIH/VRC) [E] < (b) (6) Meeker, David (b) (6) Menetski, Joseph
 (FNIH) [T] (b) (6) Messonnier, Nancy (CDC/DDID/NCIRD/OD) (Pandya, Hitesh
 (b) (6) Pangalos, Mene (b) (6) >; Pao, William
 (b) (6) Parker, Ashley (NIH/OD) [E] (b) (6) Paul, Steve (b) (6)
 Perlmutter, Roger (b) (6) Plenge, Robert (b) (6) >; Plump, Andy
 (b) (6) Rachel Ramoni (b) (6) ; Reed, John (b) (6) Reese,
 David (b) (6) ; Rouse, Doris (b) (6) ; Santos, Michael (FNIH) [T] (b) (6)
 Skovronsky, Daniel (b) (6) Stein, Peter (FDA/CDER) < (b) (6) Stoffels, Paul
 (b) (6) >; Tabak, Lawrence (NIH/OD) [E] (b) (6) >; Talley, Michael
 < (b) (6) ; Tsai, John (b) (6) >; Vessey, Rupert < (b) (6) Virgin, Skip
 (b) (6) ; Wholley, David (FNIH) [T] (b) (6) >; Woodcock, Janet (FDA/CDER)
 (b) (6) Young, John (b) (6) ; Colvis, Christine (NIH/NCATS) [E]
 (b) (6) Desrosiers, Betsy (b) (6) Eric Hughes
 (b) (6) Jansen, Kathrin (b) (6) >; Kurilla, Michael (NIH/NCATS) [E]
 (b) (6) Lowy, Douglas (NCI) < (b) (6) Read, Sarah (NIH/NIAID) [E] < (b) (6)
 Young, John < (b) (6) Adam, Stacey (FNIH) [T] < (b) (6) Margaret Anderson
 < (b) (6) ; Appell, Evan (b) (6) ; Chen, Helen Q. (b) (6) ;
 Connelly, Sarah (b) (6) ; Gonzalez, Nina < (b) (6) >; Hawk, Harrison
 < (b) (6) Mendelson, Jesse < (b) (6) Menetski, Joseph (FNIH) [T]
 (b) (6) ; Nasr, Hana (b) (6) >; Santos, Michael (FNIH) [T] < (b) (6) >; Sorosa,
 Alex David < (b) (6) >; Stratton, Benjamin (b) (6) >; btolman (b) (6)
 Tountas, Karen (FNIH) [T] (b) (6) Wachtel, Jonathan < (b) (6) Wholley, David (FNIH) [T]
 (b) (6)
Cc: Anderson, James (NIH/OD) [E] (b) (6) >; Austin, Christopher (NIH/NCATS) [E]
 (b) (6) Burklow, John (NIH/OD) [E] (b) (6) ; Carluccio, Dana
 (b) (6) >; Castillejos, Carlos (b) (6) FNIH Central Account
 (b) (6) >; Hallett, Adrienne (NIH/OD) [E] (b) (6) Lane, Cliff (NIH/NIAID) [E]
 (b) (6) >; Myles, Renate (NIH/OD) [E] < (b) (6) >; Parker, Ashley (NIH/OD) [E]
 (b) (6) >; Tabak, Lawrence (NIH/OD) [E] < (b) (6) Wolinetz, Carrie (NIH/OD) [E]
 < (b) (6) Meltzer, Abbey (FNIH) [T] (b) (6)

Dear ACTIV Leadership Team and meeting attendees:

Attached please find the slides for our meeting **tomorrow, Wednesday, December 16, 10:00 – 11:30 a.m. Eastern U.S. Time**. The minutes from the November 19 Leadership Team call are attached to this note.

The logistics for the Zoom call, which were previously sent to you in the Outlook calendar invitation, are as follows:

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Please let Joe Menetski or Cheryl Melencio here at FNIH (copied) know if you are having any problems connecting. I look forward to a productive meeting.

Regards,

David

David Wholley
Senior Vice-President, Research Partnerships
Foundation for the National Institutes of Health

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In 2019, the FNIH earned the highest rating from Charity Navigator for the fifth consecutive year and was recognized as an organization that exceeds industry standards.

From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 6/17/2020 12:47:07 PM
To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Draghia-Akli, Ruxandra [(b) (6) Eisner, Mark [(b) (6) Gottesdiener, Keith [(b) (6) Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Kim, Elizabeth [(b) (6) LaVange, Lisa [(b) (6) Levy, Elliot [(b) (6) Mellors, John W [(b) (6) Menon, Sandeep [(b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Patel, Naimish [(b) (6) Peppercorn, Amanda [(b) (6) Poole, Mike [(b) (6) Proschan, Michael (NIH/NIAID) [E] [(b) (6)]; Read, Sarah (NIH/NIAID) [E] [(b) (6) Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcd28414883d0b6996d677257-wholleyd]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Collins, Sylvia (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylva.Coli]; Amanda Peppercorn [(b) (6) Garner, Carl [(b) (6) Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Timothy Burgess [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=52e5e03dcbc847709eaab64457efa57e-TimothyBurg]; Reineck, Lora (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a62d88ba0c3b44e3bb922236c61304b3-reineckla]; Aggarwal, Neil (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c9de6615504ff9889f3b0c44a63526-aggarwalnr]; Rosenberg, Yves (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a5cb3e9a3a2747c38c42f68f5c8e40cf-rosenbey]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Brown, Jeremy (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce971eefec944a68a94add3b24835f5-brownj7]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Jacqueline Kirchner [(b) (6) Beigel, John (NIH) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=492ae062f7d74e3cbd894e30160869f0-jbeigel]; Phillips, L Revell CIV

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(b) (6) Sizemore, Christine (NIH/FIC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=05494833e0fc47a9acac194cd338b201-csizemore]
CC: Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy
[(b) (6) Jansen, Kathrin [(b) (6) Kurilla, Michael (NIH/NCATS) [E]
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI)
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Young, John
(b) (6) Biggs, Mary [(b) (6) Butcher, Tina [(b) (6)
Demarcus [(b) (6) Macone, Erin [(b) (6) Melencio, Cheryl (FNIH) [T]
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Salathin, Carla
[(b) (6) Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group
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[T] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Wachtel, Jonathan
(b) (6) Tolman, Brett [(b) (6) Alvarez, Rosa [(b) (6)
Gonzalez, Nina [(b) (6) Dana Carluccio [(b) (6) Rose Li Central
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[(b) (6) Stratton, Benjamin [(b) (6)
(b) (6) Mollica, Linda /US [(b) (6) Qashu, Felicia (NIH/OD) [E]
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(NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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(FYDIBOHF23SPDLT)/cn=Recipients/cn=8801b022ef974bf7bda8fd06f67002cf-qingchen.de]; Wung, Peter /US
[(b) (6) Hoots, W. Keith (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=328221d5416d4fc59262c6c2eca59d4c-hootswk]; Groesch, Mary (NIH/NHLBI)
[E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=69ab77a4c9bf499383186b9d9870344e-groeschm]; Shipp, Allan (NIH/NHLBI)
[E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=16001e8ab49c4489aef107bd0ce27715-shippa]; Kindzelski, Andrei
(NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=8bda5194bdca4d2594626f6313d2db5c-kindzelskia]; Hone, David M (Dave)
CIV DTRA J9 (USA) [(b) (6) Reisler, Ronald B CTR USARMY DOD JPEO CBRND (USA)
[(b) (6) Elsaid, Olivia [(b) (6) Walker, Paula (NIH/NINDS) [E]
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(FYDIBOHF23SPDLT)/cn=Recipients/cn=fbe81b9b832e40acbf5fd03bcfd32930-walkerp1]; Bethany Stokes
[(b) (6) Sorosa, Alex David [(b) (6) Lumsden, Joanne (NIH/NCATS)
[C] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=1be900c2388d41f48e3f2cbcb2fed349-lumsdenjm]; Freire, Maria (FNIH) [T]
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]

Subject: ACTIV Therapeutics-Clinical Working Group Meeting

Attachments: Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment;
Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment;
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Location: <https://fnih.zoom.us/j/> (b) (6)

Start: 6/25/2020 5:00:00 PM

End: 6/25/2020 6:00:00 PM

Show Time As: Tentative

Recurrence: Weekly

Occurs every Thursday from 1:00 PM to 2:00 PM effective 6/25/2020 until 12/31/2020.

Required Attendees: Adam, Stacey (FNIH) [T]; Bozzette, Sam (NIH/NCATS) [E]; Butterson, Joan; De Claro, R. Angelo (FDA/CDER); Draghia-

Akli, Ruxandra; Eisner, Mark; Gottesdiener, Keith; Hughes, Eric; Judy Currier; Kim, Elizabeth; LaVange, Lisa; Levy, Elliot; Mellors, John; Menon, Sandeep; Parker, Ashley (NIH/OD) [E]; Patel, Naimish; Peppercorn, Amanda; Poole, Mike; Proschan, Michael; Read, Sarah; Santos, Michael (FNIH) [T]; Shen, Yuan Li (FDA/CDER); Stein, Peter (FDA/CDER); Wholley, David (FNIH) [T]; Buchman, Tim (OS/ASPR/BARDA) (CTR); Collins, Sylva (FDA/CDER); Amanda Peppercorn; Garner, Carl; Higgs, Elizabeth (NIH/NIAID) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Timothy Burgess; Reineck, Lora (NIH/NHLBI) [E]; Aggarwal, Neil (NIH/NHLBI) [E]; Rosenberg, Yves (NIH/NHLBI) [E]; Goff, David (NIH/NHLBI) [E] (b) (6) Brown, Jeremy (NIH/NINDS) [E]; Gadbois, Ellen (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]; Jacqueline Kirchner; Beigel, John (NIH) [E]; Phillips, L Revell CIV DTRA RD (USA); Petrovick, Martha - 0449 - MITLL; (b) (6) Sizemore, Christine (NIH/FIC) [E]

Optional Attendees: Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Young, John; Biggs, Mary; Butcher, Tina; Demarcus; Macone, Erin; Melencio, Cheryl (FNIH) [T]; Salathin, Carla; Tountas, Karen (FNIH) [T]; Menetski, Joseph (FNIH) [T]; James, Stephanie (FNIH) [T]; Wachtel, Jonathan; Tolman, Brett; Alvarez, Rosa; Gonzalez, Nina; Dana Carluccio; Rose Li Central Account; Margaret Anderson; Lucas Smalldon; Stratton, Benjamin; (b) (6) Mollica, Linda /US; Qashu, Felicia (NIH/OD) [E]; Patterson, Amy (NIH/NHLBI) [E]; Rubin, Daniel B. (FDA/CDER); Marston, Hilary (NIH/NIAID) [E]; Chen, Helen Q.; Wung, Peter /US; Hoots, W. Keith (NIH/NHLBI) [E]; Groesch, Mary (NIH/NHLBI) [E]; Shipp, Allan (NIH/NHLBI) [E]; Kindzelski, Andrei (NIH/NHLBI) [E]; Hone, David M (Dave) CIV DTRA J9 (USA); Reisler, Ronald B CTR USARMY DOD JPEO CBRND (USA); Freire, Maria (FNIH) [T]; Elsaid, Olivia; Walker, Paula (NIH/NINDS) [E]; Bethany Stokes; Sorosa, Alex David; Lumsden, Joanne (NIH/NCATS) [C]

Stacey Adam is inviting you to a scheduled Zoom meeting.

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To: Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Hild, Sheri (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=edd7f1939fb94be3bf063f925ac15f02-hildsa]; (b) (6)
 (b) (6) (b) (6) (b) (6) (b) (6)
 (b) (6) Baric, Ralph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.email];
 (b) (6) Ottinger, Elizabeth (NIH/NCATS) [E] (b) (6) Colvis, Christine (NIH/NCATS) [E] (b) (6) Hewitt, Judith (NIH/NIAID) [E] (b) (6) Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda];
 (b) (6) (b) (6) (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf];
 (b) (6) Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; Rao, Srinivas (b) (6) Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Tomas Cihlar [(b) (6) Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA) (b) (6) Punturieri, Antonello (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ca7f3106e5f24b5cb5e933c6ee7a6bc7-punturiera]; Charette, Marc (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7fa2baf951848b5bf1f76a049a0eca6-charettemf]; Fessel, Josh (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=294e2bb481d94b83a1917f15338dfe19-fesseljp]; (b) (6)
 (b) (6)
CC: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcd28414883d0b6996d677257-wholleyd]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabcd2247548e596778304f781f-austinc]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy [(b) (6) Jansen, Kathrin (b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Alvarez, Rosa Maria [(b) (6) Kim, Elizabeth (b) (6) Tolman, Brett (b) (6) Wachtel, Jonathan (b) (6) Prabhavathi Fernandes (b) (6) Rose Li (b) (6) Dana Carluccio (b) (6) Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagoses]; Jonson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Gonzalez, Nina
 (b) (6) Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Burrus-Shaw, Cyndi
 (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Rodriguez, Robin D
 (b) (6) Dave Frankowski (b) (6) Baric, Toni C
 (b) (6) Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative
 Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; Florence, Clint
 (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Nancy Haigwood
 [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=03d589f440d84691ac0a530e4ba6ceb5-haigwoon.oh]; Stratton, Benjamin
 (b) (6) Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Hawk, Harrison
 (b) (6) Mason, Stephen (b) (6) (b) (6)
 Connelly, Sarah (b) (6) (b) (6) .com; Lumsden, Joanne (NIH/NCATS) [C]
 [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=1be900c2388d41f48e3f2cbcb2fed349-lumsdenjm]; FNIH
 (b) (6) Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; K C Kent Lloyd
 (b) (6) Diamond, Michael (b) (6) Eric Hughes [/o=ExchangeLabs/ou=Exchange
 Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]

Start: 12/2/2020 3:00:00 PM
End: 12/2/2020 4:00:00 PM

Recurrence: (none)

Required Attendees: Menetski, Joseph (FNIH) [T]; Hild, Sheri (NIH/OD) [E]; (b) (6) (b) (6)
 (b) (6) (b) (6) (b) (6) (b) (6) (b) (6)
 (b) (6) (b) (6) (b) (6) (b) (6)
 (b) (6) (b) (6) (b) (6) (b) (6) Parker,
 Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; (b) (6) Adams, Peter
 (OS/ASPR/BARDA); Rao, Srinivas; Qashu, Felicia (NIH/OD) [E]; Tomas Cihlar; Pitt, Margaret L CIV USARMY MEDCOM
 USAMRIID (USA); Punturieri, Antonello (NIH/NHLBI) [E]; Charette, Marc (NIH/NHLBI) [E]; Fessel, Josh (NIH/NHLBI) [E];
 (b) (6) (b) (6)
Optional Attendees: Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Colvis, Christine
 (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas
 (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T];
 James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi
 Fernandes; Diamond, Michael; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha
 (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D;
 Dave Frankowski; Baric, Toni C; Lowy, Douglas (NIH/NCI) [E]; Florence, Clint (NIH/NIAID) [E]; Nancy Haigwood;
 Stratton, Benjamin; Gadbois, Ellen (NIH/OD) [E]; Anderson, James (NIH/OD) [E]; Hawk, Harrison; Mason, Stephen;
 (b) (6) Connelly, Sarah; (b) (6) Lumsden, Joanne (NIH/NCATS) [C];
 FNIH

From: Appell, Evan [(b) (6)]
Sent: 11/5/2020 7:44:52 PM
To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Draghia-Akli, Ruxandra [(b) (6)]; Eisner, Mark [(b) (6)]; Gottesdiener, Keith [(b) (6)]; Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; LaVange, Lisa [(b) (6)]; Levy, Elliot [(b) (6)]; Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Menon, Sandeep [(b) (6)]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Patel, Naimish [(b) (6)]; Peppercorn, Amanda [(b) (6)]; Poole, Mike [(b) (6)]; Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcd28414883d0b6996d677257-wholleyd]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Collins, Sylvia (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylvia.Coll]; Amanda Peppercorn [(b) (6)]; Garner, Carl [(b) (6)]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96c8ff8ca9-ehiggs]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Timothy Burgess [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=52e5e03dcbc847709eaab64457efa57e-TimothyBurg]; Reineck, Lora (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a62d88ba0c3b44e3bb922236c61304b3-reineckla]; Aggarwal, Neil (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c9de6615504ff9889f3b0c44a63526-aggarwalnr]; Rosenberg, Yves (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a5cb3e9a3a2747c38c42f68f5c8e40cf-roosenbey]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Brown, Jeremy (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce971eefec944a68a94add3b24835f5-brownj7]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Jacqueline Kirchner

[(b) (6) Beigel, John (NIH) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=492ae062f7d74e3cbd894e30160869f0-jbeigel]; Phillips, L Revell CIV DTRA RD (USA) [(b) (6) Petrovick, Martha - 0449 - MITLL [(b) (6) Sizemore, Christine (NIH/FIC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=05494833e0fc47a9acac194cd338b201-csizemore]

CC: Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy [(b) (6) Jansen, Kathrin [(b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Young, John [(b) (6) Biggs, Mary [(b) (6) Butcher, Tina [(b) (6) Demarcus [(b) (6) Macone, Erin [(b) (6) Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Salathin, Carla [(b) (6) Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Dana Carluccio [(b) (6) Rose Li Central Account [(b) (6) Lucas Smalldon [(b) (6)]; [(b) (6) Mollica, Linda /US [(b) (6) Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Marston, Hilary (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab30660917b942ffba9ae95d631116f3-marstonhd]; Chen, Helen Q. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user34aa917e]; Wung, Peter /US [(b) (6) Hoots, W. Keith (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=328221d5416d4fc59262c6c2eca59d4c-hootswk]; Groesch, Mary (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=69ab77a4c9bf499383186b9d9870344e-groeschm]; Shipp, Allan (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=16001e8ab49c4489aef107bd0ce27715-shippa]; Kindzelski, Andrei (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8bda5194bdca4d2594626f6313d2db5c-kindzelskia]; Hone, David M (Dave) CIV DTRA J9 (USA) [(b) (6) Reisler, Ronald B CTR USARMY DOD JPEO CBRND (USA) [(b) (6) Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremcc]

Subject: RE: ACTIV Therapeutics-Clinical Working Group Meeting

Attachments: ACTIV_TX-Clinical_Working Group Meeting Guide_20201105_vF.pdf

Hi All,

Thank you for attending our TX-Clinical Working Group meeting this afternoon. Please see attached for the materials that we reviewed, and the presentation now also includes two new slides showing the demographic breakdowns for ACTIV-2/3.

Please let us know if you have any questions, and thank you all for your support.

Best,
Evan

Evan Appell

Deloitte Consulting LLP

Mobile: + (b) (6)

(b) (6)

-----Original Appointment-----

From: Adam, Stacey (FNIH) [T] < (b) (6) >

Sent: Monday, August 31, 2020 10:34 AM

To: Adam, Stacey (FNIH) [T]; Appell, Evan; Bozzette, Sam (NIH/NCATS) [E]; Butterson, Joan; De Claro, R. Angelo (FDA/CDER); Draghia-Akli, Ruxandra; Eisner, Mark; Gottesdiener, Keith; Hughes, Eric; Judy Currier; Kim, Elizabeth; LaVange, Lisa; Levy, Elliot; Mellors, John W; Menon, Sandeep; Parker, Ashley (NIH/OD) [E]; Patel, Naimish; Peppercorn, Amanda; Poole, Mike; Proschan, Michael (NIH/NIAID) [E]; Read, Sarah (NIH/NIAID) [E]; Santos, Michael (FNIH) [T]; Shen, Yuan Li (FDA/CDER); Stein, Peter (FDA/CDER); Wholley, David (FNIH) [T]; Buchman, Tim (OS/ASPR/BARDA) (CTR); Collins, Sylva (FDA/CDER); Amanda Peppercorn; Garner, Carl; Higgs, Elizabeth (NIH/NIAID) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Timothy Burgess; Reineck, Lora (NIH/NHLBI) [E]; Aggarwal, Neil (NIH/NHLBI) [E]; Rosenberg, Yves (NIH/NHLBI) [E]; Goff, David (NIH/NHLBI) [E]; Brown, Jeremy (NIH/NINDS) [E]; Gadbois, Ellen (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]; Jacqueline Kirchner; Beigel, John (NIH) [E]; Phillips, L Revell CIV DTRA RD (USA); Petrovick, Martha - 0449 - MITLL;

(b) (6); Sizemore, Christine (NIH/FIC) [E]

Cc: Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Young, John; Biggs, Mary; Butcher, Tina; Demarcus; Macone, Erin; Melencio, Cheryl (FNIH) [T]; Salathin, Carla; Tountas, Karen (FNIH) [T]; Menetski, Joseph (FNIH) [T]; James, Stephanie (FNIH) [T]; Wachtel, Jonathan; Tolman, Brett; Alvarez, Rosa Maria; Gonzalez, Nina; Dana Carluccio; Rose Li Central Account; Anderson, Margaret; Lucas Smalldon; Stratton, Benjamin; (b) (6); Mollica, Linda /US; Qashu, Felicia (NIH/OD) [E]; Patterson, Amy (NIH/NHLBI) [E]; Rubin, Daniel B. (FDA/CDER); Marston, Hilary (NIH/NIAID) [E]; Chen, Helen Q.; Wung, Peter /US; Hoots, W. Keith (NIH/NHLBI) [E]; Groesch, Mary (NIH/NHLBI) [E]; Shipp, Allan (NIH/NHLBI) [E]; Kindzelski, Andrei (NIH/NHLBI) [E]; Hone, David M (Dave) CIV DTRA J9 (USA); Reisler, Ronald B CTR USARMY DOD JPEO CBRND (USA); Freire, Maria (FNIH) [T]; Elsaid, Olivia

Subject: ACTIV Therapeutics-Clinical Working Group Meeting

When: Thursday, November 5, 2020 1:00 PM-2:00 PM (UTC-05:00) Eastern Time (US & Canada).

Where: <https://fnih.zoom>. (b) (6)

-----Original Appointment-----

From: Adam, Stacey (FNIH) [T] < (b) (6) >

Sent: Wednesday, June 17, 2020 8:48 AM

To: Adam, Stacey (FNIH) [T]; Bozzette, Sam (NIH/NCATS) [E]; Butterson, Joan; De Claro, R. Angelo (FDA/CDER); Draghia-Akli, Ruxandra; Eisner, Mark; Gottesdiener, Keith; Hughes, Eric; Judy Currier; Kim, Elizabeth; LaVange, Lisa; Levy, Elliot; Mellors, John W; Menon, Sandeep; Parker, Ashley (NIH/OD) [E]; Patel, Naimish; Peppercorn, Amanda; Poole, Mike; Proschan, Michael (NIH/NIAID) [E]; Read, Sarah (NIH/NIAID) [E]; Santos, Michael (FNIH) [T]; Shen, Yuan Li (FDA/CDER); Stein, Peter (FDA/CDER); Wholley, David (FNIH) [T]; Buchman, Tim (OS/ASPR/BARDA) (CTR); Collins, Sylva (FDA/CDER); Amanda Peppercorn; Garner, Carl; Higgs, Elizabeth (NIH/NIAID) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Timothy Burgess; Reineck, Lora (NIH/NHLBI) [E]; Aggarwal, Neil (NIH/NHLBI) [E]; Rosenberg, Yves (NIH/NHLBI) [E]; Goff, David (NIH/NHLBI) [E]; Brown, Jeremy (NIH/NINDS) [E]; Gadbois, Ellen (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]; Jacqueline Kirchner; Beigel, John (NIH) [E]; Phillips, L Revell CIV DTRA RD (USA); Petrovick, Martha - 0449 - MITLL; (b) (6); Sizemore, Christine (NIH/FIC) [E]

Cc: Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Young, John; Biggs, Mary; Butcher, Tina; Demarcus; Macone, Erin; Melencio, Cheryl (FNIH) [T]; Salathin, Carla; Tountas, Karen (FNIH) [T]; Menetski, Joseph (FNIH) [T]; James, Stephanie (FNIH) [T]; Wachtel, Jonathan; Tolman, Brett; Alvarez, Rosa Maria; Gonzalez, Nina; Dana Carluccio; Rose Li Central Account; Anderson, Margaret; Lucas Smalldon;

Stratton, Benjamin; (b) (6) Mollica, Linda /US; Qashu, Felicia (NIH/OD) [E]; Patterson, Amy (NIH/NHLBI) [E]; Rubin, Daniel B. (FDA/CDER); Marston, Hilary (NIH/NIAID) [E]; Chen, Helen Q.; Wung, Peter /US; Hoots, W. Keith (NIH/NHLBI) [E]; Groesch, Mary (NIH/NHLBI) [E]; Shipp, Allan (NIH/NHLBI) [E]; Kindzelski, Andrei (NIH/NHLBI) [E]; Hone, David M (Dave) CIV DTRA J9 (USA); Reisler, Ronald B CTR USARMY DOD JPEO CBRND (USA); Freire, Maria (FNIH) [T]; Elsaid, Olivia
Subject: ACTIV Therapeutics-Clinical Working Group Meeting
When: Occurs every Thursday effective 6/25/2020 until 12/31/2020 from 1:00 PM to 2:00 PM Eastern Standard Time.
Where: [\(b\) \(6\)](https://fnih.zoom.us/j/(b)(6))

Stacey Adam is inviting you to a scheduled Zoom meeting.

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From: Menetski, Joseph (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5001AF52DC4A427EA3D34F1E072F8CB7-MENETSKIJP]
Sent: 9/20/2020 6:43:38 PM
To: (b) (6); (b) (6); (b) (6); (b) (6); Hild, Sheri (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=edd7f1939fb94be3bf063f925ac15f02-hildsa]; (b) (6); (b) (6); (b) (6); (b) (6); Baric, Ralph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.email]; (b) (6); Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7adfcdb42cbb4014d9b26af30cc-jhewitt]; Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda]; (b) (6); (b) (6); Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; (b) (6); Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; Rao, Srinivas [(b) (6); Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Tomas Cihlar [(b) (6); Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA) [(b) (6); Punturieri, Antonello (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ca7f3106e5f24b5cb5e933c6ee7a6bc7-punturiera]; Charette, Marc (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7fa2baf951848b5bf1f76a049a0eca6-charettemf]; Fessel, Josh (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=294e2bb481d94b83a1917f15338dfe19- (b) (6);
CC: Diamond, Michael [(b) (6); Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcd28414883d0b6996d677257-wholleyd]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabcd2247548e596778304f781f-austinc]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy [(b) (6); Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Jansen, Kathrin [(b) (6); Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Alvarez, Rosa Maria

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user706e5647]; Kim, Elizabeth [(b) (6)] btolman [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user7b137a1e]; Wachtel, Jonathan (b) (6) Prabhavathi Fernandes [(b) (6)] Rose Li (b) (6) Dana Carluccio (b) (6) Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagos]; Jonson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Rodriguez, Robin D (b) (6) ; Dave Frankowski [(b) (6)] Baric, Toni C [(b) (6)] Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; Florence, Clint (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Nancy Haigwood [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=03d589f440d84691ac0a530e4ba6ceb5-haigwoon.oh]; Stratton, Benjamin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=usere3ed7188]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Hawk, Harrison [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user280c84f8]; Mason, Stephen (b) (6) (b) (6)

Subject: RE: ACTIV Preclinical full working group
Attachments: 2020-09-16_Preclinical_WG_Summary_F1.docx

Dear Team,

Here are the minutes from this weeks' meeting. Please let me know if you have any questions or concerns.

Thank you,

Best regards,
Joe

Joseph P. Menetski Ph.D.
Associate Vice President, Research Partnerships
Foundation for the National Institutes of Health
(b) (6) | fnihi.org
11400 Rockville Pike, Suite 600, North Bethesda, MD 20852



Donate to the FNIH's Pandemic Response Fund to combat COVID-19: fnihi.org/pandemic



From: Tountas, Karen (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=40C04FEF6F1E46F5B750753CD5A14F93-TOUNTASKH]
Sent: 7/10/2020 5:58:52 PM
To: Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]
Subject: RE: ACTIV Clinical Trial Capacity survey dashboard

Hi Michelle,

You're probably not spending a lot of time using the ACTIV dashboard, but I was wondering whether you have taken a look lately and what you think? Have you heard comments from anyone – positive is always welcome, and constructive criticism will help improve the user experience.

Many thanks!
Karen

From: Culp, Michelle (NIH/OD) [E] <(b) (6)>
Sent: Friday, May 22, 2020 11:38 AM
To: Wachtel, Jonathan <(b) (6)>; Gadbois, Ellen (NIH/OD) [E] <(b) (6)>
Cc: Tountas, Karen (FNIH) [T] <(b) (6)>
Subject: RE: ACTIV Clinical Trial Capacity survey dashboard

Thanks. I got in!

From: Wachtel, Jonathan <(b) (6)>
Sent: Friday, May 22, 2020 10:28 AM
To: Culp, Michelle (NIH/OD) [E] <(b) (6)>; Gadbois, Ellen (NIH/OD) [E] <(b) (6)>
Cc: Tountas, Karen (FNIH) [T] <(b) (6)>
Subject: FW: ACTIV Clinical Trial Capacity survey dashboard
Importance: High

Michelle/Ellen

Access granted. Please find the link below.

Best,

Jonathan Wachtel
Deloitte Consulting LLP
Tel/Direct: (b) (6)
www.deloitte.com

From: Tountas, Karen (FNIH) [T] <(b) (6)>
Sent: Wednesday, May 20, 2020 4:13 PM
To: Bascles, Lionel <(b) (6)>; Cohen, Myron <(b) (6)>; Corey, Larry <(b) (6)>; Victoria Davey <(b) (6)>; Desrosiers, Betsy <(b) (6)>; Dickens, Jim (NIH/NCATS) [C] <(b) (6)>; Doroshow, James (NIH/NCI) [E] <(b) (6)>; Garner, Carlos <(b) (6)>; Goff, David (NIH/NHLBI) [E] <(b) (6)>; Kurilla, Michael (NIH/NCATS) [E] <(b) (6)>; Mensah, George (NIH/NHLBI) [E] <(b) (6)>; Nayak, Seema (NIH/NIAID) [E] <(b) (6)>; Payton, Manizhe (NIH/NIAID) [E] <(b) (6)>; Resnansky, Laura <(b) (6)>; Sizemore, Christine (NIH/FIC) [E]

(b) (6) >; Srinivasan, Badhri <(b) (6)>; Stein, Peter (FDA/CDER)
(b) (6) ; Vincent, Mike (b) (6) ; Weinmann, Gail (NIH/NHLBI) [E]
<(b) (6)>
Cc: Wachtel, Jonathan (b) (6) >; Footer, Kevin (b) (6) Jones, Ethan
(b) (6) ; Long, Alyssa (b) (6)
Subject: [EXT] ACTIV Clinical Trial Capacity survey dashboard
Importance: High

Dear Colleagues,

BLUF*: The ACTIV Clinical Trial Capacity survey dashboard is ready for use
Caveat – Now for those with NIH credential, and in a few days for those external to the NIH system

After several unforeseen technical issues with both the data and the infrastructure, the clinical network and site the dashboard is ready for use. A big thank you to Jonathan and Kevin and the team at Deloitte for putting this dashboard together. We're not letting them off the hook that easily – they already are working on incorporating the CRO-SMO survey data.

For those of you with NIH credentials, you will be able to access the dashboard through this link:
<https://analyticsqa.niaid.nih.gov/#/site/ACTIV/views/ACTIVCTCWGSurveyDashboard/Network-SiteMap?iid=1>. You will find four tabs at the top of the page: 1) Network-Site Map, a dashboard with the map (sites and COVID-19 data, by USA with county-level data or world-wide, country-level views) and the network and site filters; 2) Network Detail Dashboard, a one-page summary of the network based on the survey responses; 3) Glossary, a few definitions that we have been using; and, 4) Resources that might be of interest. I have poked around the dashboard a bit – use is fairly intuitive, but if you have questions please feel free to reach out to Kevin, Ethan, or Alyssa (copied on this email). However, please note that the dashboard is “hot off the press” so if you notice any issues with the dashboard, or would like to pass along thoughts that might improve the user experience, please bring them to the attention of Kevin, Ethan, or Alyssa.

The team is working on getting everyone else on the WG access, targeting the end of this week. Apparently, this has proved a bit more challenging for the NIH group that hosts this platform than anticipated.

As you all know,
Karen

Karen H. Tountas, PhD
Scientific Program Manager
Foundation for the National Institutes of Health
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From: Santos, Michael (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AB38CB6836DE44E18EF4CC6952F65F80-SANTOSMR]
Sent: 6/1/2020 4:48:17 AM
To: (b) (6) Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; (b) (6) Arvin, Ann [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3bbf6108d53148f684dad333fce983de-aarvin.stan]; Beth Bell (b) (6) [(b) (6) (b) (6) Cavalieri Marco [(b) (6) (b) (6) (b) (6) (b) (6) Greg Glenn [(b) (6) (b) (6) Haynes, Barton [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5d4a05845b5b4069ad0447fb60ebfa79-hayne002.mc]; hotez@bcm.edu; (b) (6) Marks, Peter (FDA/CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b2e527bdba2b4a86b8d72f06b813d471-MarksP.fda]; Mascola, John (NIH/VRC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f78b40a596b4ca4a2850a429d1ae3f2-jmascola]; Messonnier, Nancy (CDC/DDID/NCIRD/OD) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=441f65db836c4a89a42aecb9a0d9b96c-NAR5]; Michael, Nelson L CIV USARMY MEDCOM WRAIR (USA) [(b) (6) Offit, Paul [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cbd9cc56fde4598a57b423d484dcf9f-offit.email]; (b) (6) Seals, Jonathan (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d7a87d49ccb4e3caaf5eb5d3586b1cc-Jonathan.Se]; (b) (6) Tal Zaks [(b) (6) (b) (6) (b) (6) Cohen, Myron [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2141b9e28c1a421fb3c1c4f75dd4c457-myron_cohen]; Denny, Joshua (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cdb4626dabbb45aa8b8e5d21169344e6-dennyjc]; (b) (6) Erbeling, Emily (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e976ebf7b14142fbb3c5c294efb334fe-erbelingej]; (b) (6) (b) (6) Gruber, Marion (FDA/CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ebf7a8eb8dd541b2883a966ea5afd809-GRUBER.fda]; (b) (6) Hamilton, Holli (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a28fc2f8eb134b00b5eaa422d0576cc-Holli.Hamil]; (b) (6) (b) (6) Ledgerwood, Julie (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5dc9f31ded594eff8ac506d2c4103c15-ledgerwood]; M (b) (6) ; Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; Marks, Peter (FDA/CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b2e527bdba2b4a86b8d72f06b813d471-MarksP.fda]; Marovich, Mary (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bfd0192d165d4643accf6347728dbaeb-marovichma]; Mascola, John (NIH/VRC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f78b40a596b4ca4a2850a429d1ae3f2-jmascola]; (b) (6) (b) (6) Kathleen Neuzil [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=33958e1252cf4266bffc8d94988f5715-kneuzil.com]; Offit, Paul [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cbd9cc56fde4598a57b423d484dcf9f-offit.email]; (b) (6) (b) (6) Laurent Humeau [(b) (6) Schrag, Stephanie (CDC/DDID/NCIRD/DBD) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9be29b344ba14363bdecaa43582ca226-ZHA6]; Verani, Jennifer R. (CDC/DDID/NCIRD/DBD) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7c249692151d46d6ac80cb28ada3d3a0-qzr7]; Hotez, Peter Jay [(b) (6) (b) (6) (b) (6) Tal Zaks [(b) (6) (b) (6) Greg Glenn [(b) (6) (b) (6)

CC: Tolman, Brett [(b) (6)]; Hopps, Markay [(b) (6)]; Kozlowski, Mary (NIH/NCI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=15373a5a1d8a4fa89d49ba9c8561cc94-kozlowskimt]; Johnson, Maureen (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0cb4ad1bebe64791b0415a7eb4bf71db-johnsonr]; Jeneffer Haynes [(b) (6)]; Austin, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=292fcb760f9f4f199ebe343e08ef1781-austinsj]; Isabel Ramsey [(b) (6)]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Marston, Hilary (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab30660917b942ffba9ae95d631116f3-marstonhd]; Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskiip]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy [(b) (6)]; Hughes, Eric [(b) (6)]; Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Young, John [(b) (6)]; Hamilton, Holli (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a28fc2f8eb134b00b5eaa4222d0576cc-Holli.Hamil]; Kathleen Neuzil [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=33958e1252cf4266bffc8d94988f5715-kneuzil.som]; Schrag, Stephanie (CDC/DDID/NCIRD/DBD) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9be29b344ba14363bdecaa43582ca226-ZHA6]; Verani, Jennifer R. (CDC/DDID/NCIRD/DBD) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7c249692151d46d6ac80cb28ada3d3a0-qzr7]; Thornburg, Natalie (CDC/DDID/NCIRD/DVD) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c8d079e00a5649639c6f1425f3bb075f-nax3]; Paul Gillard [(b) (6)]; Brian Rosen [(b) (6)]; Cheryl Keech [(b) (6)]; [(b) (6)]; dana.carl [(b) (6)]; Bethany Stokes [(b) (6)]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; 'Wachtel, Jonathan' [(b) (6)]; Stratton, Benjamin [(b) (6)]; Anderson, Margaret [(b) (6)]

Dear Vaccines Working Group and Vaccines Clinical Trials Sub-Group members,

Thank you for your participation in the last meeting of the Vaccines Working Group. Attached are the notes from that meeting and the slides that Matt Biggerstaff presented.

Please let us know if you have any questions or suggestions. We look forward to engaging with you in this week's meetings.

Best regards,
Brett and Mike

Michael Santos, PhD
Associate Vice President, Science | Foundation for the National Institutes of Health

From: Santos, Michael (FNIH) [T]
Sent: Wednesday, May 27, 2020 1:12 PM
Subject: Agenda for ACTIV Vaccines Working Group meeting: Tomorrow, 28 May

Dear Vaccines Working Group and Vaccines Clinical Trials Sub-Group members,

The agenda for **Vaccines Working Group meeting** tomorrow (Thursday) at 2pm ET (11am PT / 8pm CEST) is:

- Matt Biggerstaff, from CDC's modeling team, will present on predictive modeling of incidence to inform vaccine efficacy trials
- Time permitting, we will discuss updates from the Sub-Groups

Given the importance of the first agenda item to the Vaccines Clinical Trials Sub-Group, we are inviting that group to join the meeting. The calendar invite follows this note. As a reminder, we have two meetings scheduled tomorrow, and many of you will also receive an email about the Vaccines Clinical Trials Sub-Group meeting (at 11am ET).

We also want to provide a preview of a coming set of requests: As we have previously discussed, NIAID is constituting a DSMB for the efficacy trials that are implemented with US government funding. The Vaccines Clinical Trials Sub-Group was asked for DSMB member recommendations: thanks to those who sent input. We will be sharing a list of potential DSMB members from NIAID with the Vaccines Clinical Trials Sub-Group (cc'ing the Working Group) today for feedback. Based on that feedback, NIAID will propose a list of members and alternates. We will circulate that list to the Vaccines Working Group (cc'ing the Sub-Group) for final input before NIAID finalizes the list and reaches out to proposed members. We apologize in advance for the short turn-around times that will be requested given the necessity of finalizing the DSMB members in time for an early July trial start.

We're looking forward to the meeting tomorrow. Please feel free to reach out with any questions or suggestions.

Best regards,
Brett and Mike

Michael Santos, PhD
Associate Vice President, Science
Foundation for the National Institutes of Health
(b) (6) | fnih.org
11400 Rockville Pike, Suite 600, North Bethesda, MD 20852



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[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d];
Heaton, Penny [(b) (6) James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange
Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Kenny,
Dermot [(b) (6) Kublin, James [(b) (6) Li, Rose
[(b) (6) Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group
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[E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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[(b) (6) Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative
Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Bethany Stokes
[(b) (6) Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative
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Subject: ACTIV Clinical Trial Capacity Working Group - reporting meeting
Attachments: Clinical Trial Capacity Working Group Meeting Agenda_07292020.pdf
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Start: 7/28/2020 1:00:00 PM
End: 7/28/2020 2:00:00 PM
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Required Attendees: Bascles, Lionel; Cohen, Myron; Corey, Larry; Davey, Victoria; Desrosiers, Betsy; Dickens, Jim (NIH/NCATS) [C];
Doroshov, James (NIH/NCI) [E]; Garner, Carlos; Goff, David (NIH/NHLBI) [E]; Kurilla, Mike; Mensah, George; Nayak,
Seema (NIH/NIAID) [E]; Payton, Manzine; Resnansky, Laura; Sizemore, Christine (NIH/FIC) [E]; Srinivasan, Badhri;
Stein, Peter (FDA/CDER); Takas, Therese; Vincent, Mike; Weinmann, Gail

Optional Attendees: Wachtel, Jonathan; Colvis, Christine (NIH/NCATS) [E]; Hughes, Eric; Jansen, Kathrin; Lowy, Douglas (NCI); Read, Sarah
(NIH/NIAID) [E]; Young, John; Ardiffe, Bernadette; Criffield, Robin; Hamilton, Nancy; Melencio, Cheryl (FNIH) [T];
Minnich, Beth; Mueller-Reichenstein, Petra; Pico, Dianna; Quadros, Nora; Rebecca (NIH/NCATS) Katz [E]
((b) (6) Zoe (NIH/NHLBI) Hill [C] ((b) (6) Adam, Stacey (FNIH) [T]; Anderson, Margaret;
Ashley (NIH/OD) Parker [E] ((b) (6) Carluccio, Dana; Culp, Michelle (NIH/OD) [E]; Gadbois, Ellen
(NIH/OD) [E]; Gonzalez, Nina; Heaton, Penny; James, Stephanie; Kenny, Dermot; Kublin, James; Li, Rose; Menetski,
Joseph (FNIH) [T]; Qashu, Felicia; Santos, Michael (FNIH); Tuveson, Nancy; Wholley, David (FNIH) [T]; Bethany
Stokes; Collins, Francis (NIH/OD) [E]; Wood, Gretchen (NIH/OD) [E]

Dear Colleagues, Attached, please find the agenda for this last meeting of the Clinical Trial Capacity Working Group. With best regards, Karen

Dear Clinical Trial Capacity Working group members - As the tiger teams continue to work closely with ACTIV protocol development and operations teams, and the 'playbook' development teams ramp up to quickly develop these resources, we will reduce the number of times the full WG meets in July to every other week (July 14th and 28th). Best, Karen

Karen Tountas is inviting you to a scheduled Zoom meeting.

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Sent: 5/13/2020 5:09:15 PM
To: Myles, Renate (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d317f5626934585b3692a1823c1b522-mylesr]; Burklow, John (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e57f267323b43c08be856acb5b964ca-burklowj]
CC: Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Wolinetz, Carrie (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1c655040d47346c7b04d7bc11a403ecb-wolinetzcd]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
Subject: RE: Science: Unveiling 'Warp Speed,' the White House's America-first push for a coronavirus vaccine

We also need to have a crisp answer about the relationship between ACTIV and Operation Warp Speed. And then there's the Manhattan Project 2. People are getting confused.

From: Myles, Renate (NIH/OD) [E] <(b) (6)>
Sent: Wednesday, May 13, 2020 11:18 AM
To: Collins, Francis (NIH/OD) [E] <(b) (6)> Burklow, John (NIH/OD) [E] <(b) (6)>
Cc: Tabak, Lawrence (NIH/OD) [E] <(b) (6)> Wolinetz, Carrie (NIH/OD) [E] <(b) (6)>
Wholley, David (FNIH) [T] <(b) (6)>
Subject: RE: Science: Unveiling 'Warp Speed,' the White House's America-first push for a coronavirus vaccine

I did reach out to him about the human challenge studies and asked him to correct it. He did not reach out to talk to us about ACTIV, but it appears he spoke to plenty of the WG members.

I could set up a call with Jon so you can talk through it with him (without giving away too much). Thoughts?

From: Collins, Francis (NIH/OD) [E] <(b) (6)>
Sent: Wednesday, May 13, 2020 11:10 AM
To: Myles, Renate (NIH/OD) [E] <(b) (6)> Burklow, John (NIH/OD) [E] <(b) (6)>
Cc: Tabak, Lawrence (NIH/OD) [E] <(b) (6)>; Wolinetz, Carrie (NIH/OD) [E] <(b) (6)>; Wholley, David (FNIH) [T] <(b) (6)>
Subject: FW: Science: Unveiling 'Warp Speed,' the White House's America-first push for a coronavirus vaccine

It's really unfortunate that Jon Cohen is painting a picture of some kind of conflict or duplication between ACTIV and Operation Warp Speed. That's not the case at all. He also says that ACTIV is considering human challenge trials, which is absolutely not the case. How come Jon didn't reach out to me? Do we need to consider a response?

Francis

From: Myles, Renate (NIH/OD) [E] <(b) (6)>
Sent: Wednesday, May 13, 2020 7:53 AM
To: Collins, Francis (NIH/OD) [E] <(b) (6)>; NIH Director's Executive Committee <OD-SmallStaff@mail.nih.gov>
Cc: Prince, Scott (NIH/OD) [E] <(b) (6)>; OCPLPressTeam <(b) (6)>; Kolberg, Rebecca (NIH/OD) [E] <(b) (6)>; Pelis, Kim (NIH/OD) [E] <(b) (6)>; George, Jill (NIH/OD) [E] <(b) (6)> Kuska, Bob (NIH/OD) [E] <(b) (6)>
Subject: Science: Unveiling 'Warp Speed,' the White House's America-first push for a coronavirus vaccine

Science



AP Photo/Ted S. Warren

Unveiling ‘Warp Speed,’ the White House’s America-first push for a coronavirus vaccine

By [Jon Cohen](#) May. 12, 2020 , 5:05 PM

***Science’s* COVID-19 reporting is supported by the Pulitzer Center.**

Conventional wisdom is that a vaccine for COVID-19 is at least 1 year away, but the organizers of a U.S. government push called Operation Warp Speed have little use for conventional wisdom. The project, vaguely described to date but likely to be formally announced by the White House in the coming days, will pick a diverse set of vaccine candidates and pour essentially limitless resources into unprecedented comparative studies in animals, fast-tracked human trials, and manufacturing. Eschewing international cooperation—and any vaccine candidates from China—it hopes to have 300 million doses by January 2021 of a proven product, reserved for Americans.

Those and other details, spelled out for *Science* by a government official involved with Warp Speed, have unsettled some vaccine scientists and public health experts. They’re skeptical about the timeline and hope Warp Speed will complement, rather than compete with, ongoing COVID-19 vaccine efforts, including one announced last month by the National Institutes of Health (NIH). “Duplication only leads to infighting and slowing people down,” says Nicole Lurie, former U.S. assistant secretary for preparedness and response, who advises the Coalition for Epidemic Preparedness Innovations (CEPI), a nonprofit funding and helping coordinate COVID-19 vaccine efforts. “The U.S., and others around the world, should be engaged in this competition against the virus, not against one another.”

Warp Speed, first revealed by Bloomberg News on 29 April, has so far only been outlined. President Donald Trump briefly discussed the initiative the next day, saying, “We’re going to fast track it like you’ve never seen before.” According to a CNN report on 1 May, which the source who spoke to *Science* confirmed, Warp Speed intends to deliver the first 100 million doses of a vaccine in November and another 200 million over the following 2 months.

An extraordinary 110 COVID-19 vaccines are in development, and eight candidates—four from Chinese companies—have entered small trials in people, according to an 11 May update from the World Health Organization (WHO). But

there's less than meets the eye in many of the efforts, says a vaccine veteran who asked not to be named. "Half of them are companies that have three guys, an administrative assistant, and a dog."

The idea for Warp Speed was hatched in early April, says the official, a scientist, who was given permission to discuss it with *Science* if his name was not used. "Looking around, it became clear that without a really heroic effort, none of the existing efforts to produce vaccine was going to lead us to have vaccine to prevent what looks increasingly like a second wave that could sweep come October, November," he says. Warp Speed will have three separate "virtual teams" to address development, supply and manufacturing, and distribution, led by a "core team" of a few dozen experts from government, industry, and academia.

Warp Speed has already narrowed its list of vaccine candidates to 14 and plans to push ahead with eight, the official says. "The idea for us is to pick a diversified portfolio" of vaccines made with different technologies, or platforms. Organizers were concerned that other government vaccine investment has been "heavily weighted" toward just two candidates: one made with messenger RNA encoding the coronavirus surface "spike" protein and the other using a cold-causing adenovirus to deliver the same protein's gene. Neither technology, the official notes, has yet led to approved vaccines for any disease.

The official declined to identify Warp Speed's vaccine candidates, but he stressed two key criteria: safety and the potential to make hundreds of millions of doses quickly. "We don't have time to debug manufacturing issues here," he says. By July, Warp Speed hopes to have its eight lead candidates in human trials. At the same time, it will fund a large-scale comparison of their safety and efficacy in hamsters and monkeys to help winnow down that group. "If something's really bad, we'll get rid of it," he says.

In parallel with the trials, the project will lay the groundwork for "heavy duty manufacturing" of as many as four different vaccines. More than one may prove worthy, and multiple options guard against contamination incidents and other supply concerns.

Although Warp Speed has not ruled out any type of vaccine, it will not consider ones made in China, such as the inactivated virus vaccine recently shown to protect monkeys from the coronavirus, a first. "We can't partner with Chinese companies," the official says. "That's just not going to happen." The decision was "above my pay grade," he adds. But the chosen vaccines could be made by a company that is not headquartered in the United States. (White House trade adviser Peter Navarro in a February memo to the Coronavirus Task Force championed a "Manhattan Project" for COVID-19 vaccines that would prioritize U.S.-based companies.)

Warp Speed's main goal is to protect the United States. "The attitude here is the oxygen mask approach," the official says. "We want to get our oxygen mask on first and then we're going to help the people around us." Warp Speed, he says, plans to "freely disseminate information" to other countries and share manufacturing technologies, and it may make extra doses for the world.

Many scientists and organizations have argued, however, that any proven COVID-19 vaccines should be accessible and affordable to everyone in the world at the same time. WHO and other groups on 24 April formed the Access to COVID-19 Tools Accelerator that aims to speed development of diagnostics, therapeutics, and vaccines, and ensure "equitable global access to safe, quality, effective, and affordable" products. The European Commission, in turn, organized a fundraiser on 4 May, the Coronavirus Global Response, at which world leaders from many countries and some philanthropists pledged \$8 billion; the United States did not participate. CEPI and another nonprofit group, GAVI, the Vaccine Alliance, will oversee the vaccine drive. "It's a global problem, and it needs a global solution," says Seth Berkley, who heads GAVI.

Berkley supports Warp Speed's plan to triage the many candidates, but he calls it a shortsighted mistake to rule out Chinese products, "given the fact that they're a couple of months ahead." The Bill & Melinda Gates Foundation is closely following "15 or so" vaccine candidates, including ones from China, and will support the most promising ones, adds Emilio Emini, a former vaccine developer now with the foundation. "You need to have a global portfolio so that you're not putting all your chips on one part of the roulette table," he says.

WHO has yet another ambitious COVID-19 vaccine project, the [Solidarity Trial](#), that plans to compare candidates in human studies. That effort is headed by Andrew Witty, former CEO of GlaxoSmithKline, a major vaccine manufacturer. On Monday, WHO Director-General Tedros Adhanom Ghebreyesus said there are seven or eight “top” vaccine candidates the group hopes to accelerate. What will happen with production and supply if one of these other groups and Warp Speed select the same vaccine to prioritize is unknown.

Warp Speed’s relationship to the NIH initiative, Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV), remains unclear. That project plans to coordinate clinical trials of several COVID-19 vaccines and use common institutional review boards, safety monitors, and protocols, NIH Director Francis Collins and co-authors explain in a commentary published online on 11 May by *Science*. ACTIV is also considering controversial human “challenge” studies, which would fast-track a vaccine’s evaluation by immunizing healthy people and deliberately infecting them with the new coronavirus or a weakened form of it.

When asked about the NIH effort, the Warp Speed official said there is “no conflict at all—they are working together—one intellectually (ACTIV) and one operationally (Warp Speed).” But several scientists on the ACTIV vaccine subcommittee say they know little about Warp Speed. And one member, Peter Hotez of the Baylor College of Medicine, worries about both its name and timeline, noting the antivaccine movement argues products are often rushed to market without adequate testing. “Some of the language coming out of the White House is very damaging,” says Hotez, who is part of a team making a COVID-19 vaccine candidate. As for the January delivery of 300 million doses, “I don’t see a path by which you can collect enough efficacy and safety data by the end of the year.”

Kathryn Edwards, a vaccine specialist at Vanderbilt University who is also participating in ACTIV, notes that the efficacy trials, which will ideally track symptomatic disease in areas of high transmission, also face complicated logistical issues given that many people will only have mild cases of COVID-19 or not know they are infected at all.

The official acknowledges Warp Speed is aiming high. “I know that there’s a reasonable probability that we’re going to fail,” he says. “And if we fail, I want to make sure we’ve investigated all of the different potential ways we could have gone.”

Posted in:

- [Health](#)
- [Coronavirus](#)

doi:10.1126/science.abc7056

From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 5/15/2020 3:34:45 AM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
CC: Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]
Subject: FW: Meeting notes from yesterday's ACTIV EC meeting

Flag: Follow up

I don't see any problem with this, do you? Each page is marked Confidential and Predecisional.

From: Adam, Stacey (FNIH) [T] <(b) (6)>
Sent: Thursday, May 14, 2020 10:54 PM
To: Wholley, David (FNIH) [T] <(b) (6)>
Subject: RE: Meeting notes from yesterday's ACTIV EC meeting

Hi David,

Am I allowed to share the notes with my WG? They asked today if they would be shared since the group was discussing our letter.

Thanks,
Stacey

Stacey J. Adam, PhD

Director, Cancer

Research Partnerships

Direct: (b) (6) | Mobile: (b) (6)

From: Wholley, David (FNIH) [T] (b) (6)
Sent: Thursday, May 14, 2020 10:50 PM
To: Collins, Francis (NIH/OD) [E] <(b) (6)>; Dolsten, Mikael <(b) (6)>; Fauci, Anthony (NIH/NIAID) [E] (b) (6)>; Gibbons, Gary (NIH/NHLBI) [E] (b) (6)>; Pao, William (b) (6)>; Stoffels, Paul (b) (6)>; Woodcock, Janet (FDA/CDER) (b) (6)
Cc: Colvis, Christine (NIH/NCATS) [E] (b) (6)>; Desrosiers, Betsy (b) (6)>; Hughes, Eric (b) (6)>; Jansen, Kathrin (b) (6)>; Kurilla, Michael (NIH/NCATS) [E] (b) (6)>; Lowy, Douglas (NCI) <(b) (6)>; Read, Sarah (NIH/NIAID) [E] (b) (6)>; Young, John (b) (6)>; Anderson, James (NIH/OD) [E] <(b) (6)>; Austin, Christopher (NIH/NCATS) [E] (b) (6)>; Lane, Cliff (NIH/NIAID) [E] <(b) (6)>; Parker, Ashley (NIH/OD) [E] (b) (6)>; Tabak, Lawrence (NIH/OD) [E] (b) (6)>; Wolinetz, Carrie (NIH/OD) [E] (b) (6)>; Adam, Stacey (FNIH) [T] (b) (6)>; Alvarez, Rosa (b) (6)>; Anderson, Margaret <(b) (6)>; Elsaid, Olivia (b) (6)>; Gonzalez, Nina (b) (6)>; James, Stephanie (FNIH) [T] (b) (6)>; Kim, Elizabeth (b) (6)>; Menetski, Joseph (FNIH) [T] (b) (6)>; Santos, Michael (FNIH) [T] (b) (6)>; Stratton, Ben (b) (6)>; Tolman, Brett (b) (6)>; Tountas, Karen (FNIH) [T] (b) (6)>; Wachtel, Jonathan (b) (6)>; Wholley, David (FNIH) [T] (b) (6)
Subject: Meeting notes from yesterday's ACTIV EC meeting

Dear ACTIV Executive Committee Members, Working Group Co-Chairs and guest participants:

Here are the complete notes, including action items, from yesterday's ACTIV EC meeting. Please let me know if there is anything we may have missed. In addition, I am forwarding at Janet Woodcock's request slides she mentioned describing the global landscape of studies on convalescent plasma and hyperimmune globulin.

I look forward to continued discussions on our next EC call, scheduled for next Wednesday, May 20.

David

David Wholley
Senior Vice-President, Research Partnerships
Foundation for the National Institutes of Health

(b) (6)

fnih.org

11400 Rockville Pike Suite 600 North Bethesda, MD 20852

In 2019, the FNIH earned the highest rating from Charity Navigator for the fifth consecutive year and was recognized as an organization that exceeds industry standards.

From: Austin, Christopher (NIH/NCATS) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=17597CABC42247548E596778304F781F-AUSTINC]
Sent: 10/16/2020 8:49:12 PM
To: Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Boucher, Cynthia (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c1d80fc5e664e85ae8baf6833bc1734-boucherc]; Atkinson, Jane (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d0e3e449583b40e0b5bdfccfda71ced-jatkinso]; Chang, Soju (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=99b3263e72a94bfa9ded3f82c4dae59c-changsoju]; (b) (6) [(b) (6) 'Gavin, Brian' [(b) (6) 'Sadeh, Jonathan' [(b) (6) 'Melsheimer, Rich [CNTNL]' [(b) (6) 'Beumont-Mauviel, Maria [JRDUS]' [(b) (6) 'Bharucha_David' [(b) (6) 'Ferguson_William' [(b) (6) Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; 'LaVange, Lisa M' (b) (6) Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Gardner, Bobbi (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3dd21d20185e4e46a20a6eb89c314580-gardnerbw]; 'Sandeep Menon' [(b) (6) 'Yong, Florence H' [(b) (6) 'Trank, Christina' [(b) (6) 'Moyo, Vusi' [(b) (6) Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; 'Kimmel, Bridget [JRDUS' [(b) (6) Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; Marti, Emily (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=970fb6ea63944699aa433fb034a0f63f-carlsone]; Eisnor, Derek (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae393740634d4ec9954494c0c2ef669a-Derek.Eisno]; (b) (6) [(b) (6) Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Woodcock, Janet (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebfcf48879f92169bd7644e29-Janet.Woodc]; Mason, Robin (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=77156b112de94c439dbccb6894954618-Robin.Mason]
CC: 'Montgomery, Stephanie' [(b) (6) O'Sullivan_Alexandra (b) (6) , Thomas (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4cb470e0376340ee8a234fd4331fed3d-Thomas.Stoc]; Neta Nelson [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3d10b8fd5dff411eb1d6f8f4892e27e3-nnelson.tec]; Butler, Sandy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4782eaa72024479197826e3d71d5584c-sbutler.tec]; Daniel Benjamin Jr, M.D., Ph.D. [(b) (6) Theresa Jasion [(b) (6) Molina, Daniel [(b) (6) Rose Beci [(b) (6) Lind, Brian (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=486ebcc6ebe34d08a691e66632ed5005-lindbj]; Mason, Robin (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=77156b112de94c439dbccb6894954618-Robin.Mason]; O'rourke, Anna (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4a43de8d7c474c538615405753ccfb6c-Anna.O_rour]; Lori Hudson, Ph.D. [(b) (6) "Huyen Cao" < (b) (6) ["Huyen Cao" < (b) (6) Huyen Cac (b) (6) Brody, Betty (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ecad8c87c49d4f018bd2530beaf4a30d-Betty.Brody]; Chiang, Anna

(OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group
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(OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group
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Subject: RE: 1st ACTIV-1 patient has been randomized

Flag: Follow up

Woohoo that was fast! Thank you Bill and Jane and team!

All best,
Chris

From: Bozzette, Sam (NIH/NCATS) [E] <(b) (6)>

Sent: Friday, October 16, 2020 4:48 PM

To: Boucher, Cynthia (NIH/NCATS) [E] <(b) (6)> Atkinson, Jane (NIH/NCATS) [E]

<(b) (6)> Chang, Soju (NIH/NCATS) [E] <(b) (6)> ' (b) (6)

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'Bharucha_David' <(b) (6)> 'Ferguson_William' <(b) (6)> Eric Hughes

<(b) (6)> Read, Sarah (NIH/NIAID) [E] <(b) (6)> 'LaVange, Lisa M'

<(b) (6)> Proschan, Michael (NIH/NIAID) [E] <(b) (6)> Gardner, Bobbi (NIH/NCATS) [E]

<(b) (6)> 'Sandeep Menon' <(b) (6)> 'Yong, Florence H'

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<(b) (6)> Adam, Stacey (FNIH) [T] <(b) (6)> Marti, Emily (NIH/NCATS) [E]

<(b) (6)> Eisnor, Derek (OS/ASPR/BARDA) <(b) (6)> ' (b) (6)

<(b) (6)> Austin, Christopher (NIH/NCATS) [E] <(b) (6)> Collins, Francis (NIH/OD) [E]

<(b) (6)> Woodcock, Janet (FDA/CDER) <(b) (6)> Mason, Robin (OS/ASPR/BARDA)

<(b) (6)

Cc: 'Montgomery, Stephanie' <(b) (6)> O'Sullivan_Alexandra

<(b) (6)> Stock, Thomas (HHS/IOS) <(b) (6)> Neta Nelson

<(b) (6)> Butler, Sandy <(b) (6)> Daniel Benjamin Jr, M.D., Ph.D.

<(b) (6)> Theresa Jasion <(b) (6)> Molina, Daniel <(b) (6)

Rose Beci <(b) (6)> Lind, Brian (NIH/NCATS) [E] <(b) (6)> Mason, Robin (OS/ASPR/BARDA)

<(b) (6)> O'rourke, Anna (OS/ASPR/BARDA) (CTR) <Anna. (b) (6)> Austin, Christopher

(NIH/NCATS) [E] <(b) (6)> Lori Hudson, Ph.D. <(b) (6)> "Huyen Cao"

<(b) (6)> <"Huyen Cao" <(b) (6)> Huyen Cao <(b) (6)> Brody, Betty

(OS/ASPR/BARDA) <(b) (6)> Chiang, Anna (OS/ASPR/BARDA) <(b) (6)> Schmidt, Jeffrey

(OS/ASPR/BARDA) <(b) (6)

Subject: 1st ACTIV-1 patient has been randomized

Hello:

The first patient has been randomized into ACTIV-1. Congratulations to all, especially Bill Powderly, Jane O'Halloran, and the rest of the Wash U team.

Happy weekend to all!

Sam B

Sam Bozzette, MD, PhD

Chief Medical Officer

Immediate Office of the Director

National Center for Advancing Translational Sciences

National Institutes of Health

COLL0000013978-2515826

6701 Democracy Blvd., Room 926

Bethesda, MD 20892

(Use ZIP code 20817 for overnight mail or courier)

Phone: (b) (6)

E-mail: (b) (6)

NIH NCATS: COLLABORATE. INNOVATE. ACCELERATE.

From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 1/27/2021 10:48:43 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
CC: Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]
Subject: FW: COLCORONA manuscript online

We heard the skepticism loud and clear on the ACTIV-2/3 Trial Oversight Committee call, fyi.

From: Adam, Stacey (FNIH) [T] <(b) (6)>
Sent: Wednesday, January 27, 2021 5:36 PM
To: Wholley, David (FNIH) [T] <(b) (6)> Menetski, Joseph (FNIH) [T] <(b) (6)> Freire, Maria (FNIH) [T] <(b) (6)>
Subject: FW: COLCORONA manuscript online

Hi All,

FYI, COLOCORONA results...still a little skeptical.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
Direct: (b) (6) | Mobile: (b) (6)

From: Jonathan Arm (b) (6)
Sent: Wednesday, January 27, 2021 1:31 PM
To: Trevor Mundel (b) (6); Chris Karp <(b) (6)> Dan Hartman (b) (6); Susan Hershenson (b) (6); >; Dennis Lee (b) (6); Steven Kern (b) (6); >; Thea Norman <(b) (6)> Ian Hudson (b) (6); >; Lynda, Stuart (b) (6); Ken Duncan <(b) (6)> >; Katie Newhall <(b) (6)> >; Kedest Tesfagiorgis <(b) (6)> >; Mike Poole <(b) (6)> Robin Mogg <(b) (6)> Brad Wilken <(b) (6)> Murray Lumpkin <(b) (6)> >; Scott Miller (b) (6); >; Peter Dull (b) (6); >; Jared Silverman (b) (6); >; Jintanat Ananworanich <(b) (6)> Penny Heaton (b) (6); >; Mike Dunne (b) (6); Nathalie Strub-Wourgaft (b) (6); Adam, Stacey (FNIH) [T] (b) (6); >; Farhad Imam (b) (6); >; Valerie Mizrahi (b) (6); Dr. Gagandeep Kang (b) (6); (b) (6); Susan Fisher (b) (6); (b) (6); Ramnik Xavier (b) (6); (b) (6); >; Souleymane Mboup (b) (6)

Subject: FW: COLCORONA manuscript online

Colchicine paper is now on-line in medrxiv.

Please circulate as appropriate

Dear Jean-Claude Tardif,

Your preprint 10.1101/2021.01.26.21250494 has posted on medRxiv: <https://medrxiv.org/cgi/content/short/2021.01.26.21250494v1>

A portable graphical link to your paper (QR code) can be obtained here: <https://connect.medrxiv.org/qr/2021.01.26.21250494>. If the code is placed, for example, on a poster, your paper can be accessed through a mobile device's QR code reader.

If in future a version of this manuscript is published in a journal, medRxiv will usually automatically link the preprint to the published version within approximately two (2) weeks of journal publication. The corresponding author should receive an email from medRxiv providing notification that the link has been added. On rare occasions a match is not made because the title or authors have changed. Please wait 2-3 weeks before contacting medRxiv staff should the link not appear.

The medRxiv Team

From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 7/30/2020 2:47:45 AM
To: Plenge, Robert [(b) (6)]
CC: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
Subject: Re: [EXTERNAL] Materials for July 29 ACTIV Executive Committee Teleconference

Hi Robert:

(b) (4)

Regards,
David

From: Plenge, Robert < (b) (6) >
Sent: Wednesday, July 29, 2020 7:33 AM
To: Wholley, David (FNIH) [T] (b) (6) ; Collins, Francis (NIH/OD) [E] <col (b) (6) >
Subject: Re: [EXTERNAL] Materials for July 29 ACTIV Executive Committee Teleconference

Given the recent genetic data ([here](#), [here](#), [here](#), [here](#)), is it worth considering more routine genetic testing (e.g., GWAS, WES) in ACTIV trials to guide future repurposing?

From: "Melencio, Cheryl (FNIH) [T]" < (b) (6) > on behalf of "Wholley, David (FNIH) [T]"
(b) (6)
Date: Tuesday, July 28, 2020 at 10:55 PM
To: "Austin, Christopher (NIH/NCATS) [E]" < (b) (6) > ; "Bancel, Stephane" < (b) (6) > ; "Carter, Kara" < (b) (6) > ; "Cavaleri, Marco" < (b) (6) > ; "Cihlar, Tomas" < (b) (6) > ; "Collins, Francis (NIH/OD) [E]" < (b) (6) > ; "Corey, Larry" < (b) (6) > ; "Culp, Michelle (NIH/OD) [E]" < (b) (6) > ; "Disbrow, Gary (OS/ASPR/BARDA)" < (b) (6) > ; "Dolsten, Mikael" < (b) (6) > ; "Erbelding, Emily (NIH/NIAID) [E]" < (b) (6) > ; "Erck, Stan" < (b) (6) > ; "Fauci, Anthony (NIH/NIAID) [E]" < (b) (6) > ; "Freire, Maria (FNIH) [T]" < (b) (6) > ; "Gadbois, Ellen (NIH/OD) [E]" < (b) (6) > ; "Gibbons, Gary (NIH/NHLBI) [E]" < (b) (6) > ; "Hudson, Thomas" < (b) (6) > ; "James, Stephanie (FNIH) [T]" < (b) (6) > ; "Johnson, Robert (OS/ASPR/BARDA)" < (b) (6) > ; "Kramer, Lynn" < (b) (6) > ; "Lane, Cliff (NIH/NIAID) [E]" < (b) (6) > ; "Lepore, John" < (b) (6) > ; "Marks, Peter (FDA/CBER)" < (b) (6) > ; "Marston, Hilary (NIH/NIAID) [E]" < (b) (6) > ; "Mascola, John (NIH/VRC) [E]" < (b) (6) > ; "Meeker, David" < (b) (6) > ; "Menetski, Joseph (FNIH) [T]" < (b) (6) > ; "Messonnier, Nancy (CDC/DDID/NCIRD/OD)" < (b) (6) > ; "Pandya, Hitesh" < (b) (6) > ; "Pangalos, Mene" < (b) (6) > ; "Pao, William" < (b) (6) > ; "Parker, Ashley (NIH/OD) [E]" < (b) (6) > ; "Paul, Steve" < (b) (6) > ; "Perlmutter, Roger" < (b) (6) > ; "Plenge, Robert" < (b) (6) >

< (b) (6) "Plump, Andy" (b) (6) >, Rachel Ramoni
 (b) (6) >, "Rasi, Guido" (b) (6) "Reed, John"
 (b) (6) >, "Reese, David" < (b) (6) "Rouse, Doris" < (b) (6) "Santos,
 Michael (FNIH) [T]" (b) (6) >, "Skovronsky, Daniel" < (b) (6) >, "Stein, Peter
 (FDA/CDER)" (b) (6) "Stoffels, Paul" (b) (6) "Tabak, Lawrence (NIH/OD)
 [E]" (b) (6) >, "Talley, Michael" (b) (6) >, "Tsai, John"
 (b) (6) "Vessey, Rupert" < (b) (6) "Virgin, Skip" (b) (6) >,
 "Wholley, David (FNIH) [T]" < (b) (6) "Woodcock, Janet (FDA/CDER)"
 (b) (6) >, "Young, John" (b) (6) >, "Colvis, Christine (NIH/NCATS)
 [E]" < (b) (6) "Desrosiers, Betsy" (b) (6) >, Eric Hughes
 (b) (6) "Jansen, Kathrin" (b) (6) "Kurilla, Michael (NIH/NCATS)
 [E]" (b) (6) "Lowy, Douglas (NCI)" (b) (6) "Read, Sarah (NIH/NIAID) [E]"
 (b) (6) , "Young, John" (b) (6)
 Cc: "Bianchi, Diana (NIH/NICHD) [E]" < (b) (6) >, "Byrnes, Noni (NIH/CSR) [E]"
 (b) (6) >, "Glass, Roger (NIH/FIC) [E]" (b) (6) >, "Hodes, Richard (NIH/NIA) [E]"
 (b) (6) "Koob, George (NIH/NIAAA) [E]" (b) (6) "Koroshetz, Walter
 (NIH/NINDS) [E]" (b) (6) >, "Langevin, Helene (NIH/NCCIH) [E]"
 < (b) (6) "Norris, Andrea (NIH/CIT) [E]" (b) (6) "Perez-Stable, Eliseo
 (NIH/NIMHD) [E]" (b) (6) >, "Rodgers, Griffin (NIH/NIDDK) [E]"
 (b) (6) >, "Schwetz, Tara (NIH/OD) [E]" (b) (6) "Sharpless, Norman
 (NIH/NCI) [E]" (b) (6) >, "Tucci, Debara (NIH/NIDCD) [E]" (b) (6)
 "Tumminia, Santa (NIH/NEI) [E]" (b) (6) >, "Volkow, Nora (NIH/NIDA) [E]"
 (b) (6) >, "Woychik, Rick (NIH/NIEHS) [E]" < (b) (6) "Adam, Stacey (FNIH) [T]"
 < (b) (6) "Alvarez, Rosa" < (b) (6) "Anderson, Margaret"
 < (b) (6) "Chen, Helen" < (b) (6) "Elsaid, Olivia"
 (b) (6) >, "Gonzalez, Nina" < (b) (6) "James, Stephanie (FNIH) [T]"
 (b) (6) "Menetski, Joseph (FNIH) [T]" < (b) (6) "Santos, Michael (FNIH) [T]"
 (b) (6) "Stratton, Ben" <bst (b) (6) "Tolman, Brett" (b) (6)
 "Tountas, Karen (FNIH) [T]" (b) (6) >, "Wachtel, Jonathan" < (b) (6) "Wholley,
 David (FNIH) [T]" (b) (6) "Anderson, James (NIH/OD) [E]" (b) (6)
 "Burklow, John (NIH/OD) [E]" < (b) (6) "Castillejos, Carlos" (b) (6) >, "Culp,
 Michelle (NIH/OD) [E]" (b) (6) >, FNIH Central Account (b) (6) >, "Freire,
 Maria (FNIH) [T]" < (b) (6) "Gadbois, Ellen (NIH/OD) [E]" < (b) (6) gov>, "Wolinetz,
 Carrie (NIH/OD) [E]" (b) (6) "Burklow, John (NIH/OD) [E]" (b) (6)
 "Gorman, Greta (FNIH) [T]" (b) (6) >, "Hallett, Adrienne (NIH/OD) [E]"
 (b) (6) "Meltzer, Abbey (FNIH) [T]" < (b) (6) >, "Myles, Renate (NIH/OD) [E]"
 (b) (6) >, "Melencio, Cheryl (FNIH) [T]" (b) (6)

Subject: [EXTERNAL] Materials for July 29 ACTIV Executive Committee Teleconference

Resent-From: (b) (6)

[Use CAUTION when opening links/attachments]

Dear ACTIV EC members, Working Group Co-Chairs, and meeting participants:

Please see attached the PowerPoint slides, including the agenda, for our meeting (via Zoom) from 2:30 PM to 4:00 PM Eastern U.S. time tomorrow, Wednesday July 29. I have also attached notes from our July 1 Leadership Team meeting as well as our last ACTIV EC meeting on July 15.

The Zoom meeting information is:

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Find your local number: <https://fnih.zoom.us/> (b) (6)

Please let Joe Menetski or Cheryl Melencio here at FNIH (copied) know if you are having any problems connecting. I look forward to a productive meeting.

Regards,

David

David Wholley
Senior Vice-President, Research Partnerships
Foundation for the National Institutes of Health

(b) (6)

fnih.org

11400 Rockville Pike Suite 600 North Bethesda, MD 20852

In 2019, the FNIH earned the highest rating from Charity Navigator for the fifth consecutive year and was recognized as an organization that exceeds industry standards.

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From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 4/9/2020 5:28:03 PM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Austin, Christopher (NIH/NCATS) [E] [(b) (6) Bright, Rick [(b) (6) Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Corey, Larry [(b) (6) Disbrow, Gary (OS/ASPR/BARDA) [(b) (6) Dolsten, Mikael [(b) (6) Erbeling, Emily (NIH/NIAID) [E] [(b) (6) James, Stephanie (FNIH) [T] [(b) (6) Lane, Cliff (NIH/NIAID) [E] [(b) (6) .gov]; Marks, Peter (FDA/CBER) [(b) (6) Marston, Hilary (NIH/NIAID) [E] [(b) (6) Mascola, John (NIH/VRC) [E] [(b) (6) Meeker, David [(b) (6) Menetski, Joseph (FNIH) [T] [(b) (6) Pao, William [(b) (6) Paul, Steve [(b) (6) Perlmutter, Roger [(b) (6) Plump, Andy [(b) (6) Rasi, Guido [(b) (6) ; Reed, John [(b) (6) Rouse, Doris [(b) (6) Santos, Michael (FNIH) [T] [(b) (6) Stein, Peter (FDA/CDER) [(b) (6)]; Stoffels, Paul [(b) (6) Tabak, Lawrence (NIH/OD) [E] [(b) (6)]; Tsai, John [(b) (6) Vessey, Rupert [(b) (6) Virgin, Skip [(b) (6) Woodcock, Janet (FDA/CDER) [(b) (6) Young, John [(b) (6) Parker, Ashley (NIH/OD) [E] [(b) (6)]; Gladman, Jordan (NIH/OD) [E] [(b) (6) Colvis, Christine (NIH/NCATS) [E] [(b) (6) Desrosiers, Betsy [(b) (6) Hughes, Eric [(b) (6)]; Jansen, Kathrin [(b) (6) Hudson, Thomas [(b) (6) Kurilla, Michael (NIH/NCATS) [E] [michael.kurilla@nih.gov]; Lowy, Douglas (NCI) [(b) (6) Read, Sarah (NIH/NIAID) [E] [(b) (6) Johnson, Robert (OS/ASPR/BARDA) [(b) (6) Pandya, Hitesh [(b) (6) Skovronsky, Daniel [(b) (6) Freire, Maria (FNIH) [T] [(b) (6) Fauci, Anthony (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=df38103d75134f658ae2d356f0396b94-afauci]; Pangalos, Mene [(b) (6)
CC: Barasch, Kimberly (NIH/NIAID) [C] [(b) (6) Conrad, Patricia (NIH/NIAID) [E] [(b) (6) Hoffstetter, Renata (FNIH) [T] [(b) (6) ; Iberdemaj, Vaide [(b) (6) Melencio, Cheryl (FNIH) [T] [(b) (6) Protasiewicz, Ann [(b) (6) Thomas, Ashley (FDA/CDER) [(b) (6)]; Wood, Gretchen (NIH/OD) [E] [(b) (6)]; Burrus-Shaw, Cyndi (NIH/OD) [E] [(b) (6) Simon, Dina (NIH/OD) [C] [(b) (6)]; Lagos, Enrique (NIH/NCATS) [E] [(b) (6) McManus, Ayanna (NIH/OD) [E] [(b) (6) Adam, Stacey (FNIH) [T] [(b) (6) Li, Rose [(b) (6) Tountas, Karen (FNIH) [T] [(b) (6) Zottoli, Jessica [(b) (6) Gonzalez, Nina [(b) (6) Anderson, Margaret [(b) (6) Robert Plenge [(b) (6) Stratton, Ben [(b) (6) Alvarez, Rosa [(b) (6) Kim, Elizabeth [e (b) (6) Wachtel, Jonathan [(b) (6) Tolman, Brett [(b) (6) Mammen, Mathai [JJCUS] [(b) (6) Lowy, Douglas (NIH/NCI) [E] [(b) (6) Giorgi Sara [(b) (6) FNIH Central Account [(b) (6) Lucas Smalldon [(b) (6) Tierney, Julia (FDA/CBER) [(b) (6)]; Sepulveda, Dorina (FNIH) [T] [(b) (6)
Subject: ACTIV response partnership leadership team meeting #2
Location: <https://zoom.us/> (b) (6)
Start: 4/22/2020 2:00:00 PM
End: 4/22/2020 3:00:00 PM
Show Time As: Tentative

Required Attendees: Austin, Christopher (NIH/NCATS) [E]; Bright, Rick; Collins, Francis (NIH/OD) [E]; Corey, Larry; Disbrow, Gary (OS/ASPR/BARDA); Dolsten, Mikael; Erbelding, Emily (NIH/NIAID) [E]; Fauci, Anthony (NIH/NIAID) [E]; James, Stephanie (FNIH) [T]; Lane, Cliff (NIH/NIAID) [E]; Marks, Peter (FDA/CBER); Marston, Hilary (NIH/NIAID) [E]; Mascola, John; Meeker, David; Menetski, Joseph (FNIH) [T]; Pangalos, Mene; Pao, William; Paul, Steve; Perlmutter, Roger; Plump, Andy; Rasi, Guido; Reed, John; Rouse, Doris; Santos, Michael (FNIH) [T]; Stein, Peter (FDA/CDER); Stoffels, Paul; Tabak, Lawrence (NIH/OD) [E]; Tsai, John; Vessey, Rupert; Virgin, Skip; Woodcock, Janet (FDA/CDER); Young, John; Parker, Ashley (NIH/OD) [E]; Gladman, Jordan (NIH/OD) [E]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Hudson, Thomas; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Johnson, Robert (OS/ASPR/BARDA); Pandya, Hitesh; Skovronsky, Daniel;

(b) (6) (b) (6) Freire, Maria (FNIH) [T]

Optional Attendees: Barasch, Kimberly (NIH/NIAID) [C]; Conrad, Patricia (NIH/NIAID) [E]; Hoffstetter, Renata (FNIH) [T]; Iberdemaj, Vaide; Melencio, Cheryl (FNIH) [T]; Protasiewicz, Ann; Thomas, Ashley (FDA/CDER); Wood, Gretchen (NIH/OD) [E]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Simon, Dina (NIH/OD) [C]; Lagos, Enrique (NIH/NCATS) [E]; McManus, Ayanna (NIH/OD) [E]; Adam, Stacey (FNIH) [T]; Li, Rose; Tountas, Karen (FNIH) [T]; Zottoli, Jessica; Gonzalez, Nina; Anderson, Margaret; Robert Plenge; Stratton, Ben; Alvarez, Rosa; Kim, Elizabeth; Wachtel, Jonathan; Tolman, Brett; Mammen, Mathai [JJCUS]; Lowy, Douglas (NIH/NCI) [E]; Giorgi Sara; FNIH Central Account; Lucas Smalldon; Tierney, Julia; Sepulveda, Dorina (FNIH) [T]

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From: Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415BB86087D08B628E6F-MELENCIOC]
on behalf of Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 12/15/2020 11:28:33 PM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabcd42247548e596778304f781f-austinc]; Bancel, Stephane [(b) (6) Carter, Kara [(b) (6) Cavaleri, Marco [(b) (6) Cihlar, Tomas [(b) (6) ; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Corey, Larry [lcorey@fredhutch.org]; Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Victoria Davey [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c8291f38ec342f895243c0617e115ec-victoria.da]; Disbrow, Gary (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62a151e39ab942d88a813b449f9f6ccb-Gary.Disbro]; Dolsten, Mikael [(b) (6) Erbeling, Emily (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e976ebf7b14142fbb3c5c294efb334fe-erbelingej]; Erck, Stan [(b) (6) Fauci, Anthony (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=df38103d75134f658ae2d356f0396b94-afauci]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freirem]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Gibbons, Gary (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b71b953b50a5495ca0f2869ab13bc407-gibbonsgh]; Hudson, Thomas [(b) (6) James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Johnson, Robert (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=feb0b05457404e2f8b88af78e9ac4dd9-Robert.John]; Kramer, Lynn [(b) (6) Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Lepore, John [(b) (6) Marks, Peter (FDA/CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b2e527bdba2b4a86b8d72f06b813d471-MarksP.fda]; Marston, Hilary (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab30660917b942ffb9ae95d631116f3-marstonhd]; Mascola, John (NIH/VRC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f78b40a596b4ca4a2850a429d1ae3f2-jmascola]; Meeker, David [(b) (6)]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Messonnier, Nancy (CDC/DDID/NCIRD/OD) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=441f65db836c4a89a42aebc9a0d9b96c-NAR5]; Pandya, Hitesh [(b) (6) Pangalos, Mene [(b) (6) Pao, William [(b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Paul, Steve [(b) (6) Perlmutter, Roger [(b) (6) Plenge, Robert [(b) (6) Plump, Andy [(b) (6) Rachel Ramoni [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d3f6cb5237a44b75887b8a1ca1f9bb91-Rachel.Ramo]; Reed, John [(b) (6) Reese, David [(b) (6) Rouse, Doris [(b) (6) Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Skovronsky, Daniel [(b) (6) Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Stoffels, Paul [(b) (6) Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

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 (b) (6) Tsai, John [john. (b) (6) Vessey, Rupert [(b) (6) Virgin,
 Skip [(b) (6) Woodcock, Janet (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group
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 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Hawk,
 Harrison [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=user280c84f8]; Mendelson, Jesse (b) (6) Menetski,
 Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group
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 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userfe0939a1];
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 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userffc6da86];
 Stratton, Benjamin [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=usere3ed7188]; btolman [/o=ExchangeLabs/ou=Exchange Administrative
 Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user7b137a1e]; Tountas, Karen (FNIH) [T]
 [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan
 (b) (6)]
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 (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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 [(b) (6) Castillejos, Carlos [(b) (6) FNIH Central Account
 [(b) (6) Hallett, Adrienne (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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 [/o=ExchangeLabs/ou=Exchange Administrative Group
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 [T] [/o=ExchangeLabs/ou=Exchange Administrative Group
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Subject: RE: ACTIV Leadership Team Meeting, Tomorrow, December 16, 2020 -- CORRECTION
Attachments: 12.16 ACTIV EC and Leadership Team Meeting 20201215_vF (003).pdf; 12.16 ACTIV EC and Leadership Team Meeting_APPENDIX_20201215_vF.pdf; 2020-11-19_ACTIV_Leadership_Team_Meeting_Summary_v3.pdf

Dear ACTIV Leadership Team and meeting attendees:

Please see corrected version of materials. Sorry for the confusion.

Regards,

David

David Wholley
Senior Vice-President, Research Partnerships
Foundation for the National Institutes of Health

(b) (6)

fnihi.org

11400 Rockville Pike Suite 600 North Bethesda, MD 20852

In 2019, the FNIH earned the highest rating from Charity Navigator for the fifth consecutive year and was recognized as an organization that exceeds industry standards.

From: Melencio, Cheryl (FNIH) [T] <(b) (6)> **On Behalf Of** Wholley, David (FNIH) [T]
Sent: Tuesday, December 15, 2020 5:08 PM
To: Austin, Christopher (NIH/NCATS) [E] <(b) (6)> Bancel, Stephane
<(b) (6)> Carter, Kara <(b) (6)> Cavaleri, Marco
<(b) (6)> Cihlar, Tomas <(b) (6)> Collins, Francis (NIH/OD) [E]
<(b) (6)> Corey, Larry <(b) (6)> Culp, Michelle (NIH/OD) [E] <(b) (6)>
Victoria Davey <(b) (6)> Disbrow, Gary (OS/ASPR/BARDA) <(b) (6)> Dolsten, Mikael
<(b) (6)> Erbelding, Emily (NIH/NIAID) [E] <(b) (6)> Erck, Stan
<(b) (6)> Fauci, Anthony (NIH/NIAID) [E] <(b) (6)> Freire, Maria (FNIH) [T]
<(b) (6)> Gadbois, Ellen (NIH/OD) [E] <(b) (6)> Gibbons, Gary (NIH/NHLBI) [E]
<(b) (6)> Hudson, Thomas <(b) (6)> James, Stephanie (FNIH) [T]
<(b) (6)> Johnson, Robert (OS/ASPR/BARDA) <(b) (6)> Kramer, Lynn
<(b) (6)> Lane, Cliff (NIH/NIAID) [E] <(b) (6)> Lepore, John <(b) (6)>
Marks, Peter (FDA/CBER) <(b) (6)> Marston, Hilary (NIH/NIAID) [E] <(b) (6)>
Mascola, John (NIH/VRC) [E] <(b) (6)> Meeker, David <(b) (6)> Menetski, Joseph
(FNIH) [T] <(b) (6)> Messonnier, Nancy (CDC/DDID/NCIRD/OD) <(b) (6)> Pandya, Hitesh
<hitesh.(b) (6)> Pangalos, Mene <(b) (6)> Pao, William
<(b) (6)> Parker, Ashley (NIH/OD) [E] <(b) (6)> >; Paul, Steve <(b) (6)>
Perlmutter, Roger <(b) (6)> Plenge, Robert <(b) (6)> Plump, Andy
<(b) (6)> Rachel Ramoni <(b) (6)> Reed, John <(b) (6)> Reese,
David <(b) (6)> Rouse, Doris <(b) (6)> Santos, Michael (FNIH) [T] <(b) (6)>
Skovronsky, Daniel <(b) (6)> Stein, Peter (FDA/CDER) <(b) (6)> Stoffels, Paul
<(b) (6)> Tabak, Lawrence (NIH/OD) [E] <(b) (6)> Talley, Michael
<(b) (6)> Tsai, John <(b) (6)> Vessey, Rupert <(b) (6)> Virgin, Skip
<(b) (6)> Wholley, David (FNIH) [T] <(b) (6)> Woodcock, Janet (FDA/CDER)
<(b) (6)> Young, John <(b) (6)> Colvis, Christine (NIH/NCATS) [E]
<(b) (6)> Desrosiers, Betsy <(b) (6)> Eric Hughes
<(b) (6)> Jansen, Kathrin <(b) (6)> Kurilla, Michael (NIH/NCATS) [E]

< (b) (6) Lowy, Douglas (NCI) < (b) (6) Read, Sarah (NIH/NIAID) [E] < (b) (6)
 Young, John < (b) (6) Adam, Stacey (FNIH) [T] < (b) (6) Margaret Anderson
 < (b) (6) Appell, Evan < (b) (6) Chen, Helen Q. < (b) (6)
 Connelly, Sarah < (b) (6) Gonzalez, Nina < (b) (6) Hawk, Harrison
 < (b) (6) Mendelson, Jesse < (b) (6) Menetski, Joseph (FNIH) [T]
 < (b) (6) Nasr, Hana < (b) (6) Santos, Michael (FNIH) [T] < (b) (6) Sorosa,
 Alex David < (b) (6) Stratton, Benjamin < (b) (6) btolman < (b) (6)
 Tountas, Karen (FNIH) [T] < (b) (6) Wachtel, Jonathan < (b) (6) Wholley, David (FNIH) [T]
 < (b) (6)
Cc: Anderson, James (NIH/OD) [E] < (b) (6) Austin, Christopher (NIH/NCATS) [E]
 < (b) (6) Burklow, John (NIH/OD) [E] < (b) (6) Carluccio, Dana
 < (b) (6) Castillejos, Carlos < (b) (6) FNIH Central Account
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 < (b) (6) Tabak, Lawrence (NIH/OD) [E] < (b) (6) Wolinetz, Carrie (NIH/OD) [E]
 < (b) (6) Meltzer, Abbey (FNIH) [T] < (b) (6)
Subject: ACTIV Leadership Team Meeting, Tomorrow, December 16, 2020

Dear ACTIV Leadership Team and meeting attendees:

Attached please find the slides for our meeting **tomorrow, Wednesday, December 16, 10:00 – 11:30 a.m. Eastern U.S. Time**. The minutes from the November 19 Leadership Team call are attached to this note.

The logistics for the Zoom call, which were previously sent to you in the Outlook calendar invitation, are as follows:

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Please let Joe Menetski or Cheryl Melencio here at FNIH (copied) know if you are having any problems connecting. I look forward to a productive meeting.

Regards,

David

David Wholley

Senior Vice-President, Research Partnerships

Foundation for the National Institutes of Health

(b) (6)

fnih.org

11400 Rockville Pike Suite 600 North Bethesda, MD 20852

In 2019, the FNIH earned the highest rating from Charity Navigator for the fifth consecutive year and was recognized as an organization that exceeds industry standards.

From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 6/18/2020 6:51:49 PM
To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Judy Currier
(b) (6) Eric Hughes [(b) (6) LaVange, Lisa M [(b) (6)
Sandeep Menon [(b) (6) Proschan, Michael (NIH/NIAID) [E] [(b) (6)];
Read, Sarah (NIH/NIAID) [E] (b) (6) ; Price, Dionne (FDA/CDER) [D (b) (6) Rubin,
Daniel B. (FDA/CDER) (b) (6)]; Farley, John (FDA/CDER) (b) (6) Karen Lynn
Price [(b) (6) (b) (6) (b) (6) (b) (6) (b) (6)
(b) (6) (b) (6) (b) (6) Eron, Joe
(b) (6) Javan, Arzhang (NIH/NIAID) [E] [(b) (6) Roa, Jhoanna [(b) (6)
(b) (6) Kim, Peter (NIH/NIAID) [E] [(b) (6) Kozak, Marina (OS/ASPR/BARDA)
[(b) (6) Jhoanna Roa [(b) (6) Eron, Joseph J Jr [(b) (6)
Smith, David [(b) (6) Paul Klekotka [(b) (6) Ajay Nirula
[(b) (6) Erhardt, William (HHS/IOS) [(b) (6)
CC: Demarcus [(b) (6) Tountas, Karen (FNIH) [T] [(b) (6) Parker, Ashley (NIH/OD) [E]
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Chen, Helen Q.
[(b) (6) Lara Hosey [Lara. (b) (6) Parsons, Kelly (NIH/NIAID) [E]
[(b) (6) James Loftis, Amy [(b) (6) Joan A. Dragavon [(b) (6)
Robert W. Coombs [(b) (6) Erhardt, William (HHS/IOS) [William. (b) (6) Mishkin, Mark
(NIH/NIAID) [E] [(b) (6) .gov]; Luzar, MaryAnne (NIH/NIAID) [E] [(b) (6) Rwakazina,
Irene (NIH/NIAID) [E] [(b) (6)]; Heredia, Elizabeth (NIH/NIAID) [E] [(b) (6)
Livnat, Daniella (NIH/NIAID) [E] [(b) (6)
Subject: HOLD: ACTIV-2 Writing Team Meeting - Review of FDA Comments
Location: <https://fnih.zoom.us/> (b) (6)
Start: 6/20/2020 3:00:00 PM
End: 6/20/2020 4:00:00 PM
Show Time As: Busy

Required Attendees: Adam, Stacey (FNIH) [T]; Judy Currier; Eric Hughes; Lisa LaVange; Sandeep Menon; Proschan, Michael (NIH/NIAID) [E]; Read, Sarah (NIH/NIAID) [E]; Price, Dionne (FDA/CDER); Rubin, Daniel B. (FDA/CDER); Farley, John (FDA/CDER); Karen Lynn Price; (b) (6) (b) (6) (b) (6)
(b) (6) (b) (6) (b) (6) ; Eron, Joe; Javan, Arzhang (NIH/NIAID) [E]; Roa, Jhoanna; (b) (6) Kim, Peter (NIH/NIAID) [E]; Kozak, Marina (OS/ASPR/BARDA); Jhoanna Roa; Eron, Joseph J Jr; Smith, David; Paul Klekotka; Ajay Nirula; Erhardt, William (OS/ASA/OCIO/DCIO-Ops) (CTR)
Optional Attendees: Demarcus; Tountas, Karen (FNIH) [T]; Parker, Ashley (NIH/OD) [E]; Chen, Helen Q.; Lara Hosey; Parsons, Kelly (NIH/NIAID) [E]; James Loftis, Amy; Joan A. Dragavon; Robert W. Coombs; Erhardt, William (HHS/IOS); Mishkin, Mark (NIH/NIAID) [E]; Luzar, MaryAnne (NIH/NIAID) [E]; Rwakazina, Irene (NIH/NIAID) [E]; Heredia, Elizabeth (NIH/NIAID) [E]; Livnat, Daniella (NIH/NIAID) [E]

Stacey Adam is inviting you to a scheduled Zoom meeting.

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From: Gadbois, Ellen (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0243D1D6E6F248268D2EDEEC566C26C2A-GADBOISEL]
Sent: 8/14/2020 4:18:18 PM
To: Brodd, Lauren (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ba665dea08e54171b3d6890c2518ddb9-leponelm]
Subject: ACTIV website updates per EC slides/meeting today
Attachments: 8.14 ACTIV Executive Committee Meeting 20200814 Final to Distribute.pptx; 2020-07-15_Executive_Committee_Meeting_Summary vFinal.docx; 2020-07-29_ACTIV_Leadership_Team_Meeting_Summary final.docx

You may want to revise how the working groups are listed on the website since clinical trials capacity is done, and vaccine is suspended (may be reconvened if needed)—see slides.

From: Melencio, Cheryl (FNIH) [T] <(b) (6)> **On Behalf Of** Wholley, David (FNIH) [T]
Sent: Thursday, August 13, 2020 10:20 PM
To: Collins, Francis (NIH/OD) [E] <(b) (6)> Disbrow, Gary (OS/ASPR/BARDA) <(b) (6)>
Dolsten, Mikael <(b) (6)> Fauci, Anthony (NIH/NIAID) [E] <(b) (6)> Gibbons, Gary
(NIH/NHLBI) [E] <(b) (6)> Marks, Peter (FDA/CBER) <(b) (6)> Pao, William
<(b) (6)> Plump, Andrew <(b) (6)> Stoffels, Paul <(b) (6)>
Woodcock, Janet (FDA/CDER) <(b) (6)> Colvis, Christine (NIH/NCATS) [E]
<(b) (6)> Desrosiers, Betsy <(b) (6)> Eric Hughes
<(b) (6)> Jansen, Kathrin <(b) (6)> Kurilla, Michael (NIH/NCATS) [E]
<(b) (6)> Lowy, Douglas (NCI) <(b) (6)> Read, Sarah (NIH/NIAID) [E] <(b) (6)>
Young, John <(b) (6)> Wholley, David (FNIH) [T] <(b) (6)>
Cc: Anderson, James (NIH/OD) [E] <(b) (6)> Austin, Christopher (NIH/NCATS) [E]
<(b) (6)> Burklow, John (NIH/OD) [E] <(b) (6)> Castillejos, Carlos <(b) (6)>
Culp, Michelle (NIH/OD) [E] <(b) (6)> FNIH Central Account <(b) (6)> Freire, Maria
(FNIH) [T] <(b) (6)> Gadbois, Ellen (NIH/OD) [E] <(b) (6)> Hallett, Adrienne (NIH/OD) [E]
<(b) (6)> Lane, Cliff (NIH/NIAID) [E] <(b) (6)> Myles, Renate (NIH/OD) [E]
<(b) (6)> Parker, Ashley (NIH/OD) [E] <(b) (6)> Tabak, Lawrence (NIH/OD) [E]
<(b) (6)> Wolinetz, Carrie (NIH/OD) [E] <(b) (6)> Melencio, Cheryl (FNIH) [T]
<(b) (6)> Adam, Stacey (FNIH) [T] <(b) (6)> Alvarez, Rosa <(b) (6)>
Anderson, Margaret <(b) (6)> Chen, Helen <(b) (6)> Elsaid, Olivia
<(b) (6)> Gonzalez, Nina <(b) (6)> Hawk, Harrison <(b) (6)>
Menetski, Joseph (FNIH) [T] <(b) (6)> Santos, Michael (FNIH) [T] <(b) (6)> Stratton, Benjamin
<(b) (6)> Tolman, Brett <(b) (6)> Tountas, Karen (FNIH) [T] <(b) (6)>
Wachtel, Jonathan <(b) (6)>
Subject: Materials for August 14 ACTIV Executive Committee Teleconference
Importance: High

Dear ACTIV EC members, Working Group Co-Chairs, and meeting participants:

Please see attached the PowerPoint slides, including the agenda, for our meeting (via Zoom) from **12:00 – 1:00 PM Eastern U.S. time** tomorrow, Friday, August 14. I have also attached notes from our July 29 Leadership Team meeting as well as our last EC meeting on July 15. As you know we will be hearing from two Working Groups instead of four, **so the co-chairs have decided to make this call as well as future EC and LT calls going forward 60 minutes in length instead of 90 minutes.**

The Zoom information is:

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Please let Cheryl Melencio here at FNIH (copied) know if you are having any problems connecting. I look forward to a productive meeting.

Regards,

David

David Wholley
Senior Vice-President, Research Partnerships
Foundation for the National Institutes of Health

(b) (6)

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In 2019, the FNIH earned the highest rating from Charity Navigator for the fifth consecutive year and was recognized as an organization that exceeds industry standards.

From: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]
Sent: 1/12/2021 9:53:35 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Carter, Kara [(b) (6) Cavaleri, Marco [(b) (6) Cihlar, Tomas [(b) (6)]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Corey, Larry [(b) (6) Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Victoria Davey [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c8291f38ec342f895243c0617e115ec-victoria.da]; Disbrow, Gary (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62a151e39ab942d88a813b449f9f6ccb-Gary.Disbro]; Dolsten, Mikael [(b) (6) Erbelding, Emily (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e976ebf7b14142fbb3c5c294efb334fe-erbeldingej]; Erck, Stan [(b) (6) Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Gibbons, Gary (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b71b953b50a5495ca0f2869ab13bc407-gibbonsgh]; Hudson, Thomas [(b) (6) James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Johnson, Robert (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=feb0b05457404e2f8b88af78e9ac4dd9-Robert.John]; Kramer, Lynn [(b) (6) Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Mascola, John (NIH/VRC) [E] [(b) (6) Meeker, David [(b) (6) Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Messonnier, Nancy (CDC/DDID/NCIRD/OD) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=441f65db836c4a89a42aebc9a0d9b96c-NAR5]; Pandya, Hitesh [(b) (6) Pao, William [(b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Perlmutter, Roger [(b) (6) Plenge, Robert [(b) (6) Plump, Andy [(b) (6) Reese, David [(b) (6) Rouse, Doris [(b) (6) Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Skovronsky, Daniel [(b) (6) Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Stoffels, Paul [(b) (6) Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Talley, Michael [(b) (6) Tsai, John [(b) (6) Vessey, Rupert [(b) (6) Virgin, Skip [(b) (6) Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Woodcock, Janet (FDA/OC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebfcf48879f92169bd7644e29-Janet.Woodc]; Young, John [(b) (6) Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Burklow, John (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e57f267323b43c08be856acb5b964ca-burklowj]; Carluccio, Dana [(b) (6) Castillejos, Carlos [(b) (6) FNIH Central Account [(b) (6) Hallett, Adrienne (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1705e2e7c254b84a77f058dbf75b31b-hallettaa]; Lumsden, Joanne (NIH/NCATS) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group

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 [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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 [(b) (6) Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group
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 [(b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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 [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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 [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab9a138f1e284c689fedfb10b8cc5295-marganderso]; Appell, Evan
 [(b) (6) Chen, Helen [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=8801b022ef974bf7bda8fd06f67002cf-qingchen.de]; Connelly, Sarah
 [(b) (6) Gonzalez, Nina [(b) (6) Hawk, Harrison [(b) (6)
 Mendelson, Jesse [(b) (6) Nasr, Hana [(b) (6) Sorosa, Alex
 [/o=ExchangeLabs/ou=Exchange Administrative Group
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 [(b) (6) btolman [(b) (6)]; Wachtel, Jonathan [(b) (6)]; Embry,
 Alan (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=882a18a10a134c49acac21cb83fd599d-embrya]; Venkayya, Rajeev
 [(b) (6) Bancel, Stephane [(b) (6)
 Fauci, Anthony (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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 [(b) (6) Marks, Peter (FDA/CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group
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 [(b) (6) Paul, Steve [(b) (6) Rachel Ramoni
 [/o=ExchangeLabs/ou=Exchange Administrative Group
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 [(b) (6)
 CC: Austin, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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 (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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 (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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 [(b) (6) Coan, Amanda [(b) (6) Conrad, Patricia (NIH/NIAID) [E]
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 (NIH/NHLBI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group
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 [(b) (6) ; Fuhrer, Nicole [(b) (6) Giorgi, Sara [(b) (6)
 Hoban, Michelle [(b) (6) Hoffstetter, Renata (FNIH) [T] [/o=ExchangeLabs/ou=Exchange
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 Iberdemaj, Vaide [(b) (6) Jenkins, Christine S. [(b) (6) Lagos,
 Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagos]; Lever, Susan

[(b) (6) Magbie-Robinson, Kim (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=74a5b9cea10b4f919d9db20c8aaec3e7-magbierobin]; Martin, Melisa [(b) (6) McManus, Ayanna (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bcf06de08ba845249b9b36ad216e237e-amcmanus]; Minnich, Beth [(b) (6) Perala, Mie [(b) (6) Protasiewicz, Ann [(b) (6) Riccobene, Kim [(b) (6) Riffin, Mary [(b) (6) Ripley, Nadege [(b) (6) Schuster, Donna [(b) (6) Sepulveda, Dorina (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=675efcc8cf7b4f6986d1eb3c3ed1fd96-sepulvedade]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Suhana, Tina (NIH/VRC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=07e062bf05a14748ba3d9fb3e468057-esuhana]; Thomas, Ashley (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1bcd5d3f7c1e4309a251d013e1cc89b0-Ashley.Thom]; Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; Hughes, Karen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0e11e04daa2b44dea1a06ce7ab21cb1a-hugheskp]; Togashi, Mieko (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=136a73bd42274938aa467e738767f83e-togashim]; Underwood, Nancy [(b) (6) Zottoli, Jessica [(b) (6) Regan, Donna M [(b) (6) Vessey, Rupert [(b) (6) Burke, Leslie [(b) (6) John Lepore [(b) (6) Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; Grant, Sarah [(b) (6) Pruitt, Kim (NIH/NLM/NCBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5f43fb8970c343a38150ec1186a34f9a-pruitt]; Sherry, Steve (NIH/NLM/NCBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3339a3f0862046b78f97a029c4753bf3-sherry]; Bell, Julie [(b) (6)]

Subject: ACTIV Leadership Team Call #14

Location: <https://fnih.zoom.us/j/5442818826?pwd=bDBjZjVTWThyL3ZGNzI3aG9yWTRCZz09>

Start: 3/18/2021 2:30:00 PM

End: 3/18/2021 4:00:00 PM

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Required Attendees: Austin, Christopher (NIH/NCATS) [E]; Bancel, Stephane; Carter, Kara; Cavaleri, Marco; Cihlar, Tomas; Collins, Francis (NIH/OD) [E]; Corey, Larry; Culp, Michelle (NIH/OD) [E]; Davey, Victoria; Disbrow, Gary (OS/ASPR/BARDA); Dolsten, Mikael; Erbeling, Emily (NIH/NIAID) [E]; Erck, Stan; Fauci, Anthony (NIH/NIAID) [E]; Gadbois, Ellen (NIH/OD) [E]; Gibbons, Gary (NIH/NHLBI) [E]; Hudson, Thomas; James, Stephanie (FNIH) [T]; Johnson, Robert (OS/ASPR/BARDA); Kramer, Lynn; Lane, Cliff (NIH/NIAID) [E]; Lepore, John; Marks, Peter (FDA/CBER); Mascola, John; Meeker, David; Menetski, Joseph (FNIH) [T]; Messonnier, Nancy (CDC/DDID/NCIRD/OD); Pandya, Hitesh; Pangalos, Mene; Pao, William; Parker, Ashley (NIH/OD) [E]; Paul, Steve; Perlmutter, Roger; Plenge, Robert; Plump, Andy; Ramoni, Rachel; Reed, John; Reese, David; Rouse, Doris; Santos, Michael (FNIH) [T]; Skovronsky, Daniel; Stein, Peter (FDA/CDER); Stoffels, Paul; Tabak, Lawrence (NIH/OD) [E]; Talley, Michael; Tsai, John; Vessey, Rupert; Virgin, Skip; Wholley, David (FNIH) [T]; Woodcock, Janet (FDA/OC); Young, John; Anderson, James (NIH/OD) [E]; Burklow, John (NIH/OD) [E]; Carluccio, Dana; Castillejos, Carlos; FNIH Central Account; Hallett, Adrienne (NIH/OD) [E]; Lumsden, Joanne (NIH/NCATS) [C]; Myles, Renate (NIH/OD) [E]; Wolinetz, Carrie (NIH/OD) [E]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Meltzer, Abbey (FNIH) [T]; Adam, Stacey (FNIH) [T]; Anderson, Margaret; Appell, Evan; Chen, Helen; Connelly, Sarah; Gonzalez, Nina; Hawk, Harrison; Mendelson, Jesse; Nasr, Hana; Sorosa, Alex; Stratton, Ben; Tolman, Brett; Wachtel, Jonathan; Embry, Alan (NIH/NIAID) [E]; Venkayya, Rajeev; [(b) (6)]

Optional Attendees: Austin, Sarah (NIH/NIAID) [E]; Barasch, Kimberly (NIH/NIAID) [E]; Bell, Julie; Burrus-Shaw, Cyndi (NIH/OD) [E]; Carver, Trea (NIH) [C]; Caulfield, Anita; Coan, Amanda; Conrad, Patricia (NIH/NIAID) [E]; Dimishkov, Roxanne (NIH/NHLBI) [C];

Edl, Susan; Fuhrer, Nicole; Giorgi, Sara; Hoban, Michelle; Hoffstetter, Renata (FNIH) [T]; Iberdemaj, Vaide; Jenkins, Christine S.; Krack, Kimberly; Lagos, Enrique (NIH/NCATS) [E]; Lever, Susan; Magbie-Robinson, Kim (NIH/OD) [C]; Martin, Melisa; McManus, Ayanna (NIH/OD) [E]; Minnich, Beth; Perala, Mie; Protasiewicz, Ann; Riccobene, Kim; Riffin, Mary; Ripley, Nadege; Schuster, Donna; Sepulveda, Dorina (FNIH) [T]; Simon, Dina (NIH/OD) [C]; Suhana, Tina (NIH/VRC) [E]; Thomas, Ashley (FDA/CDER); Wood, Gretchen (NIH/OD) [E]; Hughes, Karen (NIH/OD) [E]; Togashi, Mieko (NIH/NCI) [E]; Underwood, Nancy; Zottoli, Jessica; Regan, Donna M; Vessey, Rupert; Burke, Leslie; John Lepore; Lowy, Douglas (NIH/NCI) [E]; Grant, Sarah; Pruitt, Kim (NIH/NLM/NCBI) [E]; Sherry, Steve (NIH/NLM/NCBI) [E]

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From: Adam, Stacey (FNIH) [T] [/o=EXCHANGELABS/ou=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/cn=RECIPIENTS/cn=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 5/22/2020 2:30:59 AM
To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Eric Hughes [(b) (6)]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Ruxandra Draghia-Akli [(b) (6)]; Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Naimish Patel [(b) (6)]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Young, John [(b) (6)]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Poole, Mike [(b) (6)]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Vincent, Michael [(b) (6)]; Keith Gottesdiener [(b) (6)]; Elliott Levy [(b) (6)]; Wung, Peter /US [(b) (6)]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Carlos O Garner [(b) (6)]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]
CC: Elizabeth Kim [(b) (6)]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Alvarez, Rosa Maria [(b) (6)]; Salathin, Carla [(b) (6)]; (b) (6); (b) (6); (b) (6); Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Lucas Smalldon [(b) (6)]; Walker, Paula (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fbe81b9b832e40acbf5fd03bcfd32930-walkerp1]; Ward, Jackie (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4114c7d13389454f89fe3411cb3a834f-wardjam]; Rose Li Central Account [(b) (6)]; Chen, Helen Q. [(b) (6)]
Subject: ACTIV TX-Clinical Agent Prioritization Subgroup Meeting #13
Location: <https://fnih.zoom.us> (b) (6)
Start: 5/28/2020 4:00:00 PM
End: 5/28/2020 5:00:00 PM
Show Time As: Tentative

Required Attendees: Eric Hughes; Read, Sarah (NIH/NIAID) [E]; Ruxandra Draghia-Akli; John Mellors; Naimish Patel; Colvis, Christine (NIH/NCATS) [E]; Young, John; Stein, Peter (FDA/CDER); Poole, Mike; Buchman, Tim (OS/ASPR/BARDA) (CTR); Vincent, Michael; Keith Gottesdiener; Elliott Levy; Wung, Peter /US; Koroshetz, Walter (NIH/NINDS) [E]; Higgs, Elizabeth (NIH/NIAID) [E]; Carlos O Garner; Goff, David (NIH/NHLBI) [E]
Optional Attendees: Elizabeth Kim; Menetski, Joseph (FNIH) [T]; Alvarez, Rosa Maria; Salathin, Carla; (b) (6); (b) (6); Parker, Ashley (NIH/OD) [E]; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Lucas Smalldon; Walker, Paula (NIH/NINDS) [E]; Ward, Jackie (NIH/OD) [E]; (b) (6); Rose Li Central Account; Chen, Helen Q.

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Sent: 7/23/2020 4:13:28 PM
To: Jacqueline Kirchner [(b) (6)] Garner, Carl [(b) (6)] Menon, Sandeep [(b) (6)] Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Draghia-Akli, Ruxandra [(b) (6)] Eisner, Mark [(b) (6)] Gottesdiener, Keith [(b) (6)] Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Kim, Elizabeth [(b) (6)] LaVange, Lisa [(b) (6)] Levy, Elliot [(b) (6)] Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Patel, Naimish [(b) (6)] Peppercorn, Amanda [(b) (6)] Poole, Mike [(b) (6)] Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Collins, Sylvia (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylva.Coli]; Amanda Peppercorn [(b) (6)] Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Timothy Burgess [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=52e5e03dcbc847709eaab64457efa57e-TimothyBurg]; Reineck, Lora (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a62d88ba0c3b44e3bb922236c61304b3-reineckla]; Aggarwal, Neil (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c9de6615504ff9889f3b0c44a63526-aggarwalnr]; Rosenberg, Yves (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a5cb3e9a3a2747c38c42f68f5c8e40cf-roosenbey]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Brown, Jeremy (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce971eefec944a68a94add3b24835f5-brownj7]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Beigel, John (NIH) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

CC: (FYDIBOHF23SPDLT)/cn=Recipients/cn=492ae062f7d74e3cbd894e30160869f0-jbeigel]; Phillips, L Revell CIV DTRA RD (USA) [(b) (6) Petrovick, Martha - 0449 - MITLL [(b) (6) (b) (6) Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy [(b) (6) Jansen, Kathrin [(b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Young, John (b) (6) Biggs, Mary [(b) (6) Butcher, Tina [(b) (6) Demarcus [(b) (6) Macone, Erin [(b) (6) Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa72482415bb86087d08b628e6f-melencioc]; Salathin, Carla [(b) (6) Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Wachtel, Jonathan (b) (6) Tolman, Brett [(b) (6) Alvarez, Rosa [(b) (6) Dana Carluccio [(b) (6) Rose Li Central Account [(b) (6) Anderson, Margaret [(b) (6) Lucas Smalldon [(b) (6) Stratton, Benjamin [(b) (6) (b) (6) Mollica, Linda /US [Linda.Mollica@sanofi.com]; Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Marston, Hilary (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab30660917b942ffba9ae95d631116f3-marstonhd]; Chen, Helen Q. [(b) (6) Wung, Peter /US [(b) (6) Hoots, W. Keith (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=328221d5416d4fc59262c6c2eca59d4c-hootswk]; Groesch, Mary (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=69ab77a4c9bf499383186b9d9870344e-groeschm]; Shipp, Allan (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=16001e8ab49c4489aef107bd0ce27715-shippa]; Kindzelski, Andrei (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8bda5194bdca4d2594626f6313d2db5c-kindzelskia]; Hone, David M (Dave) CIV DTRA J9 (USA) [(b) (6) Reisler, Ronald B CTR USARMY DOD JPEO CBRND (USA) [(b) (6)

Subject: ACTIV Therapeutics-Clinical Working Group Meeting
Attachments: ACTIV_TX-Clinical_Working Group Meeting Guide_20200723.pdf
Location: <https://fnih.zoom.> (b) (6)

Start: 7/23/2020 5:00:00 PM
End: 7/23/2020 6:00:00 PM
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Recurrence: Weekly
every Thursday from 1:00 PM to 2:00 PM

Required Attendees: Jacqueline Kirchner; Garner, Carl; Menon, Sandeep; Bozzette, Sam (NIH/NCATS) [E]; Butterson, Joan; De Claro, R. Angelo (FDA/CDER); Draghia-Akli, Ruxandra; Eisner, Mark; Gottesdiener, Keith; Hughes, Eric; Judy Currier; Kim,

Elizabeth; LaVange, Lisa; Levy, Elliot; Mellors, John; Parker, Ashley (NIH/OD) [E]; Patel, Naimish; Peppercorn, Amanda; Poole, Mike; Proschan, Michael; Read, Sarah; Santos, Michael (FNIH) [T]; Shen, Yuan Li (FDA/CDER); Stein, Peter (FDA/CDER); Wholley, David (FNIH) [T]; Buchman, Tim (OS/ASPR/BARDA) (CTR); Collins, Sylva (FDA/CDER); Amanda Peppercorn; Higgs, Elizabeth (NIH/NIAID) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Timothy Burgess; Reineck, Lora (NIH/NHLBI) [E]; Aggarwal, Neil (NIH/NHLBI) [E]; Rosenberg, Yves (NIH/NHLBI) [E]; Goff, David (NIH/NHLBI) [E] (b) (6) Brown, Jeremy (NIH/NINDS) [E]; Gadbois, Ellen (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]; Beigel, John (NIH) [E]; Phillips, L Revell CIV DTRA RD (USA); Petrovick, Martha - 0449 - MITLL;

(b) (6)

**Optional
Attendees:**

Gonzalez, Nina; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Young, John; Biggs, Mary; Butcher, Tina; Demarcus; Macone, Erin; Melencio, Cheryl (FNIH) [T]; Salathin, Carla; Tountas, Karen (FNIH) [T]; Menetski, Joseph (FNIH) [T]; James, Stephanie (FNIH) [T]; Wachtel, Jonathan; Tolman, Brett; Alvarez, Rosa; Dana Carluccio; Rose Li Central Account; Anderson, Margaret; Lucas Smalldon; Stratton, Benjamin; (b) (6) Mollica, Linda /US; Qashu, Felicia (NIH/OD) [E]; Patterson, Amy (NIH/NHLBI) [E]; Rubin, Daniel B. (FDA/CDER); Marston, Hilary (NIH/NIAID) [E]; Chen, Helen Q.; Wung, Peter /US; Hoots, W. Keith (NIH/NHLBI) [E]; Groesch, Mary (NIH/NHLBI) [E]; Shipp, Allan (NIH/NHLBI) [E]; Kindzelski, Andrei (NIH/NHLBI) [E]; Hone, David M (Dave) CIV DTRA J9 (USA); Reisler, Ronald B CTR USARMY DOD JPEO CBRND (USA)

Dear ACTIV TX-Clinical WG members,

Please find attached the slides for today's meeting with the agenda.
We will have a speaker from NIAID presenting on a new master protocol idea.

Thanks,
Stacey

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From: Adam, Stacey (FNIH) [T] [/o=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
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To: Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Draghia-Akli, Ruxandra [(b) (6) Eisner, Mark [(b) (6) Gottesdiener, Keith (b) (6) Hughes, Eric [(b) (6) Judy Carrier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Kim, Elizabeth [(b) (6) LaVange, Lisa [(b) (6) Levy, Elliot [(b) (6) Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Menon, Sandeep [(b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaa06ebd70-parkeras]; Patel, Naimish (b) (6) ; Peppercorn, Amanda [(b) (6) Poole, Mike [(b) (6) Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Collins, Sylvia (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylvia.Collis]; Amanda Peppercorn [(b) (6) Garner, Carl (b) (6) ; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96c8ca9-ehiggs]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Burgess, Timothy [(b) (6) Reineck, Lora (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a62d88ba0c3b44e3bb922236c61304b3-reineckla]; Aggarwal, Neil (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c9de6615504ff9889f3b0c44a63526-aggarwalnr]; Rosenberg, Yves (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a5cb3e9a3a2747c38c42f68f5c8e40cf-roosenbey]; Brown, Jeremy (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce971eefec944a68a94add3b24835f5-brownj7]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]
CC: Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy [(b) (6) Jansen, Kathrin [(b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Young, John [john. (b) (6) Biggs, Mary [(b) (6) Butcher, Tina [(b) (6) Demarcus [(b) (6) Macone, Erin [(b) (6) Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Salathin, Carla [(b) (6) Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Wachtel, Jonathan (b) (6) Tolman, Brett [(b) (6) Alvarez, Rosa [(b) (6) Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Dana Carluccio [(b) (6) Rose Li Central Account [(b) (6) Anderson, Margaret [(b) (6) Lucas Smalldon [(b) (6) Stratton, Benjamin [(b) (6) (b) (6) Mollica, Linda /US [(b) (6) Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Marston, Hilary (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab30660917b942ffba9ae95d631116f3-marstonhd]; Hoots, W. Keith (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=328221d5416d4fc59262c6c2eca59d4c-hootswk]; Mensah, George (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=284d85649e634a0a91bb0b9aac84846c-mensahga]; Kiley, James (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=eae6b96b43b4dbcbff39382168a5c86-kileyj]; Groesch, Mary (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=69ab77a4c9bf499383186b9d9870344e-groeschm]; Shipp, Allan (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=16001e8ab49c4489aef107bd0ce27715-shippa]

Subject: ACTIV TX-Clinical Working Group Meeting #8
Attachments: ACTIV_TX-Clinical_Working Group Meeting Guide_20200528.pdf
Location: https://fnih.zoom. (b) (6)

Start: 5/28/2020 5:00:00 PM
End: 5/28/2020 6:00:00 PM
Show Time As: Tentative

Required Attendees: Bozzette, Sam (NIH/NCATS) [E]; Butterson, Joan; De Claro, R. Angelo (FDA/CDER); Draghia-Akli, Ruxandra; Eisner, Mark; Gottesdiener, Keith; Hughes, Eric; Judy Currier; Kim, Elizabeth; LaVange, Lisa; Levy, Elliot; Mellors, John; Menon, Sandeep; Parker, Ashley (NIH/OD) [E]; Patel, Naimish; Peppercorn, Amanda; Poole, Mike; Proschan, Michael; Read, Sarah; Santos, Michael (FNIH) [T]; Shen, Yuan Li (FDA/CDER); Stein, Peter (FDA/CDER); Wholley, David (FNIH) [T]; Buchman, Tim (OS/ASPR/BARDA) (CTR); Collins, Sylva (FDA/CDER); Amanda Peppercorn; Garner, Carl; Higgs, Elizabeth (NIH/NIAID) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Burgess, Timothy; Reineck, Lora (NIH/NHLBI) [E]; Aggarwal, Neil (NIH/NHLBI) [E]; Rosenberg, Yves (NIH/NHLBI) [E]; Brown, Jeremy (NIH/NINDS) [E]; Gadbois, Ellen (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]
Optional Attendees: Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Young, John; Biggs, Mary; Butcher, Tina; Demarcus; Macone, Erin; Melencio, Cheryl (FNIH) [T]; Salathin, Carla;

Tountas, Karen (FNIH) [T]; Menetski, Joseph (FNIH) [T]; James, Stephanie (FNIH) [T]; Wachtel, Jonathan; Tolman, Brett; Alvarez, Rosa; Gonzalez, Nina; Dana Carluccio; Rose Li Central Account; Anderson, Margaret; Lucas Smalldon; Stratton, Benjamin; (b) (6) Mollica, Linda /US; Qashu, Felicia (NIH/OD) [E]; Patterson, Amy (NIH/NHLBI) [E]; Goff, David (NIH/NHLBI) [E] (david.goff@nih.gov); Rubin, Daniel B. (FDA/CDER); Marston, Hilary (NIH/NIAID) [E]; Hoots, W. Keith (NIH/NHLBI) [E]; Mensah, George (NIH/NHLBI) [E]; Kiley, James (NIH/NHLBI) [E]; Groesch, Mary (NIH/NHLBI) [E]; Shipp, Allan (NIH/NHLBI) [E]

Dear TX-Clinical WG,

Please find attached the slides for the meeting today. We will have some slight updates on the mAb criteria to discuss, but otherwise these are what we will use to review.

Thanks,

Stacey

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From: Santos, Michael (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AB38CB6836DE44E18EF4CC6952F65F80-SANTOSMR]
Sent: 5/21/2020 1:29:23 PM
To: Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr];
(b) (6) Lowy, Douglas (NIH/NCI) [E] [(b) (6)]; (b) (6)
Arvin, Ann [(b) (6) Beth Bell ((b) (6) [(b) (6)
(b) (6) Cavaleri Marco [(b) (6) (b) (6)
(b) (6) (b) (6) Greg Glenn [(b) (6)
(b) (6) Haynes, Barton [(b) (6) (b) (6) (b) (6)
Marks, Peter (FDA/CBER) [(b) (6) Mascola, John (NIH/VRC) [E] [(b) (6)
Messonnier, Nancy (CDC/DDID/NCIRD/OD) [(b) (6) Michael, Nelson L CIV USARMY MEDCOM WRAIR
(USA) [(b) (6) Offit, Paul [(b) (6) HSchu (b) (6) Seals, Jonathan
(OS/ASPR/BARDA) [(b) (6) (b) (6) (b) (6) Tal Zaks
[Tal. (b) (6)
CC: Tolman, Brett [(b) (6)]; (b) (6) Hopps, Markay [(b) (6)
Kozlowski, Mary (NIH/NCI) [C] [(b) (6) Johnson, Maureen (NIH/NCI) [E]
[(b) (6) (b) (6) Jeneffer Haynes [(b) (6)
(b) (6) kell (b) (6) (b) (6) Austin, Sarah (NIH/NIAID) [E]
(b) (6) (b) (6) Isabel Ramsey [(b) (6) Parker,
Ashley (NIH/OD) [E] [(b) (6) Marston, Hilary (NIH/NIAID) [E] [(b) (6)]; Qashu,
Felicia (NIH/OD) [E] [fel (b) (6) Culp, Michelle (NIH/OD) [E] [(b) (6) Gadbois, Ellen
(NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadbois]; Wholley, David (FNIH) [T]
[(b) (6) Melencio, Cheryl (FNIH) [T] [(b) (6) Menetski, Joseph (FNIH) [T]
[(b) (6) Adam, Stacey (FNIH) [T] [(b) (6) Tountas, Karen (FNIH) [T] [(b) (6)
James, Stephanie (FNIH) [T] [(b) (6) Colvis, Christine (NIH/NCATS) [E] [(b) (6)
Desrosiers, Betsy [(b) (6) Hughes, Eric [(b) (6) Kurilla, Michael
(NIH/NCATS) [E] (b) (6) ; Read, Sarah (NIH/NIAID) [E] [(b) (6) Young, John
(b) (6) Paul Gillard [(b) (6) Hamilton, Holli (OS/ASPR/BARDA)
[(b) (6) Modjarrad, Kayvon CIV USARMY MEDCOM WRAIR (USA)
(b) (6)]; Kathleen Neuzil [(b) (6) Schrag, Stephanie
(CDC/DDID/NCIRD/DBD) [(b) (6) Verani, Jennifer R. (CDC/DDID/NCIRD/DBD) [(b) (6)
Thornburg, Natalie (CDC/DDID/NCIRD/DVD) [(b) (6) Gonzalez, Nina [(b) (6) Wachtel,
Jonathan [(b) (6) Stratton, Benjamin [(b) (6) Anderson, Margaret
[(b) (6) (b) (6) (b) (6) Bethany Stokes
[(b) (6) Arvin, Ann [(b) (6) Vivek Shinde [(b) (6)

Subject: ACTIV Vaccines Working Group meeting

Location: Webex: <https://nih.webex.co> (b) (6)

Start: 6/4/2020 6:15:00 PM

End: 6/4/2020 7:15:00 PM

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Required Attendees: Santos, Michael (FNIH) [T]; (b) (6) Lowy, Douglas (NIH/NCI) [E]; (b) (6)
Arvin, Ann; Beth Bell ((b) (6) (b) (6) Cavaleri Marco; (b) (6)
(b) (6) (b) (6) Greg Glenn; (b) (6) Haynes,
Barton; (b) (6) (b) (6) Marks, Peter (FDA/CBER); Mascola, John (NIH/VRC) [E];
Messonnier, Nancy (CDC/DDID/NCIRD/OD); Michael, Nelson L CIV USARMY MEDCOM WRAIR (USA); Offit, Paul;
(b) (6) Seals, Jonathan (OS/ASPR/BARDA); (b) (6)
(b) (6) Tal Zaks
Optional Attendees: Tolman, Brett; (b) (6) Hopps, Markay; Kozlowski, Mary (NIH/NCI) [C]; Johnson, Maureen
(NIH/NCI) [E]; (b) (6) Jeneffer Haynes; (b) (6) (b) (6)
(b) (6) Austin, Sarah (NIH/NIAID) [E]; (b) (6) Isabel Ramsey; Parker,

Ashley (NIH/OD) [E]; Marston, Hilary (NIH/NIAID) [E]; Qashu, Felicia (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]; Gadbois, Ellen (NIH/OD) [E]; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Menetski, Joseph (FNIH) [T]; Adam, Stacey (FNIH) [T]; Tountas, Karen (FNIH) [T]; James, Stephanie (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Kurilla, Michael (NIH/NCATS) [E]; Read, Sarah (NIH/NIAID) [E]; Young, John; Paul Gillard; Hamilton, Holli (OS/ASPR/BARDA); Modjarrad, Kayvon CIV USARMY MEDCOM WRAIR (USA); Kathleen Neuzil; Schrag, Stephanie (CDC/DDID/NCIRD/DBD); Verani, Jennifer R. (CDC/DDID/NCIRD/DBD); Thornburg, Natalie (CDC/DDID/NCIRD/DVD); Gonzalez, Nina; Wachtel, Jonathan; Stratton, Benjamin; Anderson, Margaret;

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Bethany Stokes; Ann Arvin; Vivek Shinde

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To: Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetski.jp]; Hild, Sheri (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=edd7f1939fb94be3bf063f925ac15f02-hildsa]; (b) (6) (b) (6) Baric, Ralph
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.email]; (b) (6) Ottinger, Elizabeth (NIH/NCATS) [E] (b) (6) Colvis, Christine (NIH/NCATS) [E] (b) (6) Hewitt, Judith (NIH/NIAID) [E] (b) (6) Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda]; (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; (b) (6) Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; Rao, Srinivas (b) (6) Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Tomas Cihlar (b) (6) Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA) (b) (6) Punturieri, Antonello (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ca7f3106e5f24b5cb5e933c6ee7a6bc7-punturiera]; Charette, Marc (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7fa2baf951848b5bf1f76a049a0eca6-charettemf]; Fessel, Josh (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=294e2bb481d94b83a1917f15338dfe19-fessel.jp]; (b) (6) (b) (6) (b) (6) (b) (6)
CC: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabcd42247548e596778304f781f-austinc]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy (b) (6) Jansen, Kathrin (b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Alvarez, Rosa Maria (b) (6) Kim, Elizabeth (b) (6) btolman (b) (6) Wachtel, Jonathan (b) (6) Prabhavathi Fernandes (b) (6) Diamond, Michael (b) (6) Rose Li (b) (6) Dana Carluccio (b) (6) Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagoses]; Jonson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Gonzalez, Nina (b) (6) Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Burrus-Shaw, Cyndi

(NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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[(b) (6) Dave Frankowski [(b) (6) antoinette_baric
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(FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Hawk, Harrison
[(b) (6) Mason, Stephen [Stephen. (b) (6) caroline. (b) (6)
Connelly, Sarah [(b) (6)]; (b) (6) Lumsden, Joanne (NIH/NCATS) [C]
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[(b) (6) (b) (6) Embry, Alan (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange
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Lerner, Andrea (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=53254f4fb04e4bcbabe37940b4b41887-fennellyam]; Eric Hughes
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]

Start: 3/17/2021 2:00:00 PM
End: 3/17/2021 3:00:00 PM

Recurrence: (none)

From: Hawk, Harrison [(b) (6)]
Sent: 11/24/2020 12:15:27 AM
To: Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Hild, Sheri (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=edd7f1939fb94be3bf063f925ac15f02-hildsa]; (b) (6) m; (b) (6) (b) (6) (b) (6) (b) (6) Baric, Ralph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.email]; (b) (6) Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7adfcdb42cbb4014d9b26af30cc-jhewitt]; Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda]; (b) (6) (b) (6) (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; (b) (6) Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; Rao, Srinivas [(b) (6) Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Tomas Cihlar [(b) (6) Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA) [(b) (6) Punturieri, Antonello (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ca7f3106e5f24b5cb5e933c6ee7a6bc7-punturiera]; Charette, Marc (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7fa2baf951848b5bf1f76a049a0eca6-charettemf]; Fessel, Josh (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=294e2bb481d94b83a1917f15338dfe19-fesseljp]; (b) (6)
CC: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabcd2247548e596778304f781f-austinc]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Desrosiers, Betsy [(b) (6) Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Jansen, Kathrin [(b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Kim, Elizabeth [(b) (6) btolman [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user7b137a1e]; Wachtel, Jonathan (b) (6) Prabhavathi

Fernandes [(b) (6) Diamond, Michael [(b) (6) Rose Li
[(b) (6) Dana Carluccio [(b) (6) Lagos, Enrique (NIH/NCATS)
[E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d];
Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Burrus-Shaw, Cyndi
(NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Rodriguez, Robin D
[(b) (6) Dave Frankowski [(b) (6) antoinette_baric
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Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; Florence, Clint (NIH/NIAID)
[E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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(NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]

Subject: RE: ACTIV Preclinical full working group

Attachments: 20201123_Viral Sequence Tracking and Testing Efforts_vF.pptx

Hi All,

Ahead of our meeting on Wednesday, the preclinical team has prepared some slides that will guide our discussion on ongoing viral sequence tracking and testing efforts (attached).

On **slides 2 and 3**, you will notice that we have requested input from the working group members. Prior to our meeting, **please take a moment to review these topics** and be ready to share any thoughts you may have. We look forward to continuing the discussions we have held with many of you in this larger forum, and appreciate the time and effort you all have put towards this subject to date.

Best regards,
Harrison

-----Original Appointment-----

From: Menetski, Joseph (FNIH) [T] < (b) (6) >

Sent: Tuesday, August 4, 2020 9:10 AM

To: Menetski, Joseph (FNIH) [T]; Hawk, Harrison; Hild, Sheri (NIH/OD) [E]; (b) (6)

(b) (6); (b) (6); (b) (6); (b) (6)

(b) (6); (b) (6); (b) (6) Baric, Ralph; (b) (6)

Ottinger, Elizabeth (NIH/NCATS) [E]; Colvis, Christine (NIH/NCATS) [E]; Hewitt, Judith (NIH/NIAID) [E]; Deming, Damon

(FDA/CDER); (b) (6); (b) (6); (b) (6) Parker, Ashley (NIH/OD) [E];

Collins, Francis (NIH/OD) [E]; (b) (6); Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas; Qashu,

Felicia (NIH/OD) [E]; Tomas Cihlar; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA); Punturieri, Antonello

(NIH/NHLBI) [E]; Charette, Marc (NIH/NHLBI) [E]; Fessel, Josh (NIH/NHLBI) [E]; (b) (6)

Cc: Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Desrosiers, Betsy;

Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E];

Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Diamond, Michael; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski; Baric, Toni C; Lowy, Douglas (NIH/NCI) [E]; Florence, Clint (NIH/NIAID) [E]; Nancy Haigwood; Stratton, Benjamin; Gadbois, Ellen (NIH/OD) [E]; Anderson, James (NIH/OD) [E]

Subject: ACTIV Preclinical full working group

When: Wednesday, November 25, 2020 10:00 AM-11:00 AM (UTC-05:00) Eastern Time (US & Canada).

Where: <https://fnih.zoom.us/j> (b) (6)

-----Original Appointment-----

From: Menetski, Joseph (FNIH) [T] <(b) (6)>

Sent: Tuesday, April 14, 2020 6:44 PM

To: Menetski, Joseph (FNIH) [T]; Hild, Sheri (NIH/OD) [E]; (b) (6)

(b) (6)
(b) (6) Baric, Ralph; (b) (6) Ottinger, Elizabeth (NIH/NCATS) [E]; Colvis, Christine (NIH/NCATS) [E]; Hewitt, Judith (NIH/NIAID) [E]; Deming, Damon (FDA/CDER); (b) (6); Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; (b) (6); Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas; Qashu, Felicia (NIH/OD) [E]; Tomas Cihlar; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA); Punturieri, Antonello (NIH/NHLBI) [E]; Charette, Marc (NIH/NHLBI) [E]; Fessel, Josh (NIH/NHLBI) [E]; (b) (6)

Cc: Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Diamond, Michael; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski; Baric, Toni C; Lowy, Douglas (NIH/NCI) [E]; Florence, Clint (NIH/NIAID) [E]; Nancy Haigwood; Stratton, Benjamin; Gadbois, Ellen (NIH/OD) [E]; Anderson, James (NIH/OD) [E]

Subject: ACTIV Preclinical full working group

When: Occurs every Wednesday effective 4/22/2020 until 12/23/2020 from 10:00 AM to 11:00 AM Eastern Standard Time.

Where: <https://fnih.zoom.us/j> (b) (6)

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 10/1/2020 4:44:54 PM
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Subject: ACTIV Therapeutics-Clinical Working Group Meeting

Attachments: ACTIV_TX-Clinical_Working Group Meeting Guide_20201001_vF.pdf

Location: <https://fnih.zoom.us/> (b) (6)

Start: 10/1/2020 5:00:00 PM

End: 10/1/2020 6:00:00 PM

Show Time As: Tentative

Recurrence: Weekly

every Thursday from 1:00 PM to 2:00 PM

Required Attendees: Levy, Elliot; Jacqueline Kirchner; Garner, Carl; Bozzette, Sam (NIH/NCATS) [E]; Butterson, Joan; De Claro, R. Angelo (FDA/CDER); Draghia-Akli, Ruxandra; Eisner, Mark; Gottesdiener, Keith; Hughes, Eric; Judy Currier; Kim, Elizabeth; LaVange, Lisa; Mellors, John; Menon, Sandeep; Parker, Ashley (NIH/OD) [E]; Patel, Naimish; Peppercorn, Amanda; Poole, Mike; Proschan, Michael; Read, Sarah; Santos, Michael (FNIH) [T]; Shen, Yuan Li (FDA/CDER); Stein, Peter (FDA/CDER); Wholley, David (FNIH) [T]; Buchman, Tim (OS/ASPR/BARDA) (CTR); Collins, Sylva (FDA/CDER); Amanda Peppercorn; Higgs, Elizabeth (NIH/NIAID) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Timothy Burgess; Reineck, Lora (NIH/NHLBI) [E]; Aggarwal, Neil (NIH/NHLBI) [E]; Rosenberg, Yves (NIH/NHLBI) [E]; Goff, David (NIH/NHLBI) [E]; (b) (6) Brown, Jeremy (NIH/NINDS) [E]; Gadbois, Ellen (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]; Beigel, John (NIH) [E]; Phillips, L Revell CIV DTRA RD (USA); Petrovick, Martha - 0449 - MITLL; (b) (6) Sizemore, Christine (NIH/FIC) [E]

Optional Attendees: Merritt, Gabriella Marie; Margaret Anderson; Gonzalez, Nina; Kurilla, Michael (NIH/NCATS) [E]; (b) (6) Stock, Thomas (HHS/IOS); Freire, Maria (FNIH) [T]; Desrosiers, Betsy; Colvis, Christine (NIH/NCATS) [E]; Jansen, Kathrin; Lowy, Douglas (NCI); Young, John; Biggs, Mary; Butcher, Tina; Demarcus; Macone, Erin; Melencio, Cheryl (FNIH) [T]; Salathin, Carla; Tountas, Karen (FNIH) [T]; Menetski, Joseph (FNIH) [T]; James, Stephanie (FNIH) [T]; Wachtel, Jonathan; Tolman, Brett; Alvarez, Rosa; Dana Carluccio; Rose Li Central Account; Lucas Smalldon; Stratton, Benjamin; (b) (6) Mollica, Linda /US; Qashu, Felicia (NIH/OD) [E]; Patterson, Amy (NIH/NHLBI) [E]; Rubin, Daniel B. (FDA/CDER); Marston, Hilary (NIH/NIAID) [E]; Chen, Helen Q.; Wung, Peter /US; Hoots, W. Keith (NIH/NHLBI) [E]; Groesch, Mary (NIH/NHLBI) [E]; Shipp, Allan (NIH/NHLBI) [E]; Kindzelski, Andrei (NIH/NHLBI) [E]; Hone, David M (Dave) CIV DTRA J9 (USA); Reisler, Ronald B CTR USARMY DOD JPEO CBRND (USA); Elsaid, Olivia; Walker, Paula (NIH/NINDS) [E]; Bethany Stokes

Dear ACTIV TX-Clinical WG,

Please find attached the slides for today's presentation.

Thanks,
Stacey

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To: Garner, Carl [(b) (6)] Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Sizemore, Christine (NIH/FIC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=05494833e0fc47a9acac194cd338b201-csizemore]; Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Draghia-Akli, Ruxandra [(b) (6)] Eisner, Mark [(b) (6)] Gottesdiener, Keith [(b) (6)] Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Kim, Elizabeth [(b) (6)] LaVange, Lisa [(b) (6)] Levy, Elliot [(b) (6)] Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Menon, Sandeep [(b) (6)] Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Patel, Naimish [(b) (6)] Peppercorn, Amanda [(b) (6)] Poole, Mike [(b) (6)] Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Collins, Sylvia (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylvia.Colli]; Amanda Peppercorn [(b) (6)] Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Timothy Burgess [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=52e5e03dcbc847709eaab64457efa57e-TimothyBurg]; Reineck, Lora (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a62d88ba0c3b44e3bb922236c61304b3-reineckla]; Aggarwal, Neil (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c9de6615504ff9889f3b0c44a63526-aggarwalnr]; Rosenberg, Yves (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a5cb3e9a3a2747c38c42f68f5c8e40cf-roosenbey]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Brown, Jeremy (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce971eefec944a68a94add3b24835f5-brownj7]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Jacqueline Kirchner

[(b) (6) Beigel, John (NIH) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=492ae062f7d74e3cbd894e30160869f0-jbeigel]; Phillips, L Revell CIV DTRA RD (USA) [(b) (6) Petrovick, Martha - 0449 - MITLL [(b) (6) (b) (6)

CC: Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy [(b) (6) Jansen, Kathrin [(b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Young, John (b) (6) Biggs, Mary [(b) (6) Butcher, Tina [(b) (6) Demarcus [(b) (6) Macone, Erin [(b) (6) Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Salathin, Carla [(b) (6)]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Wachtel, Jonathan (b) (6) Tolman, Brett [(b) (6) Alvarez, Rosa [(b) (6) Dana Carluccio [(b) (6) Rose Li Central Account [(b) (6) Anderson, Margaret [(b) (6) Lucas Smalldon [(b) (6) Stratton, Benjamin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=usere3ed7188]; (b) (6) Mollica, Linda /US [(b) (6) Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Marston, Hilary (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab30660917b942ffba9ae95d631116f3-marstonhd]; Chen, Helen Q. [(b) (6) Wung, Peter /US [(b) (6) Hoots, W. Keith (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=328221d5416d4fc59262c6c2eca59d4c-hootswk]; Groesch, Mary (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=69ab77a4c9bf499383186b9d9870344e-groeschm]; Shipp, Allan (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=16001e8ab49c4489aef107bd0ce27715-shippa]; Kindzelski, Andrei (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8bda5194bdca4d2594626f6313d2db5c-kindzelskia]; Hone, David M (Dave) CIV DTRA J9 (USA) [(b) (6) Reisler, Ronald B CTR USARMY DOD JPEO CBRND (USA) [ronald. (b) (6) Elsaid, Olivia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userf0efa7bd]

Subject: ACTIV Therapeutics-Clinical Working Group Meeting
Attachments: ACTIV_TX-Clinical_Working Group Meeting Guide_20200805.pdf
Location: https://fnih.zoom. (b) (6)

Start: 8/6/2020 5:00:00 PM
End: 8/6/2020 6:00:00 PM
Show Time As: Tentative

Recurrence: Weekly
every Thursday from 1:00 PM to 2:00 PM

Required Attendees: Garner, Carl; Higgs, Elizabeth (NIH/NIAID) [E]; Sizemore, Christine (NIH/FIC) [E]; Bozzette, Sam (NIH/NCATS) [E]; Butterson, Joan; De Claro, R. Angelo (FDA/CDER); Draghia-Akli, Ruxandra; Eisner, Mark; Gottesdiener, Keith; Hughes, Eric; Judy Currier; Kim, Elizabeth; LaVange, Lisa; Levy, Elliot; Mellors, John; Menon, Sandeep; Parker, Ashley (NIH/OD) [E]; Patel, Naimish; Peppercorn, Amanda; Poole, Mike; Proschan, Michael; Read, Sarah; Santos, Michael (FNIH) [T]; Shen, Yuan Li (FDA/CDER); Stein, Peter (FDA/CDER); Wholley, David (FNIH) [T]; Buchman, Tim (OS/ASPR/BARDA) (CTR); Collins, Sylva (FDA/CDER); Amanda Peppercorn; Koroshetz, Walter (NIH/NINDS) [E]; Burgess, Timothy; Reineck, Lora (NIH/NHLBI) [E]; Aggarwal, Neil (NIH/NHLBI) [E]; Rosenberg, Yves (NIH/NHLBI) [E]; Goff, David (NIH/NHLBI) [E] (b) (6) Brown, Jeremy (NIH/NINDS) [E]; Gadbois, Ellen (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]; Jacqueline Kirchner; Beigel, John (NIH) [E]; Phillips, L Revell CIV DTRA RD (USA); Petrovick, Martha - 0449 - MITLL; (b) (6)

Optional Attendees: Freire, Maria (FNIH) [T]; Gonzalez, Nina; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Young, John; Biggs, Mary; Butcher, Tina; Demarcus; Macone, Erin; Melencio, Cheryl (FNIH) [T]; Salathin, Carla; Tountas, Karen (FNIH) [T]; Menetski, Joseph (FNIH) [T]; James, Stephanie (FNIH) [T]; Wachtel, Jonathan; Tolman, Brett; Alvarez, Rosa; Dana Carluccio; Rose Li Central Account; Anderson, Margaret; Lucas Smalldon; Stratton, Benjamin; (b) (6) Mollica, Linda /US; Qashu, Felicia (NIH/OD) [E]; Patterson, Amy (NIH/NHLBI) [E]; Rubin, Daniel B. (FDA/CDER); Marston, Hilary (NIH/NIAID) [E]; Chen, Helen Q.; Wung, Peter /US; Hoots, W. Keith (NIH/NHLBI) [E]; Groesch, Mary (NIH/NHLBI) [E]; Shipp, Allan (NIH/NHLBI) [E]; Kindzelski, Andrei (NIH/NHLBI) [E]; Hone, David M (Dave) CIV DTRA J9 (USA); Reisler, Ronald B CTR USARMY DOD JPEO CBRND (USA); Elsaid, Olivia

Dear ACTIV TX-Clinical WG,

Looking forward to speaking with you all today! Please find attached the slides with the agenda for the meeting.

Thanks,
Stacey

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 6/4/2020 2:18:42 AM
To: Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Draghia-Akli, Ruxandra [(b) (6) Eisner, Mark [(b) (6) Gottesdiener, Keith [(b) (6) Hughes, Eric [(b) (6) Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Kim, Elizabeth [(b) (6) LaVange, Lisa [(b) (6) Levy, Elliot [(b) (6) Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Menon, Sandeep [(b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Patel, Naimish [naimish.patel@sanofi.com]; Peppercorn, Amanda [(b) (6) Poole, Mike [(b) (6) Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Collins, Sylvia (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylvia.Collis]; Amanda Peppercorn [(b) (6) Garner, Carl [(b) (6) Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Timothy Burgess [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=52e5e03dc847709eaab64457efa57e-TimothyBurg]; Reineck, Lora (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a62d88ba0c3b44e3bb922236c61304b3-reineckla]; Aggarwal, Neil (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c9de6615504ff9889f3b0c44a63526-aggarwalnr]; Rosenberg, Yves (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a5cb3e9a3a2747c38c42f68f5c8e40cf-rosenbey]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Brown, Jeremy (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce971eefec944a68a94add3b24835f5-brownj7]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Jacqueline Kirchner [(b) (6)]

CC: Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy [(b) (6)] Jansen, Kathrin [(b) (6)] Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Young, John [(b) (6)] Biggs, Mary [(b) (6)] Butcher, Tina [(b) (6)] Demarcus [(b) (6)] Macone, Erin [(b) (6)] Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Salathin, Carla [(b) (6)] Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Wachtel, Jonathan [(b) (6)] Tolman, Brett [(b) (6)] Alvarez, Rosa [(b) (6)] Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Dana Carluccio [(b) (6)] Rose Li Central Account [(b) (6)] Anderson, Margaret [(b) (6)] Lucas Smalldon [(b) (6)] Stratton, Benjamin [(b) (6)] [(b) (6)] Mollica, Linda /US [(b) (6)] Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Marston, Hilary (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab30660917b942ffba9ae95d631116f3-marstonhd]; Chen, Helen Q. [(b) (6)] Wung, Peter /US [(b) (6)] Hoots, W. Keith (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=328221d5416d4fc59262c6c2eca59d4c-hootswk]

Subject: ACTIV TX-Clinical Working Group Meeting #9
Attachments: ACTIV_TX-Clinical_Working Group Meeting Guide_20200604.pdf
Location: [https://fnih.zoom.us/j/ \(b\) \(6\)](https://fnih.zoom.us/j/ (b) (6))

Start: 6/4/2020 5:00:00 PM
End: 6/4/2020 6:00:00 PM
Show Time As: Tentative

Required Attendees: Bozzette, Sam (NIH/NCATS) [E]; Butterson, Joan; De Claro, R. Angelo (FDA/CDER); Draghia-Akli, Ruxandra; Eisner, Mark; Gottesdiener, Keith; Hughes, Eric; Judy Currier; Kim, Elizabeth; LaVange, Lisa; Levy, Elliot; Mellors, John; Menon, Sandeep; Parker, Ashley (NIH/OD) [E]; Patel, Naimish; Peppercorn, Amanda; Poole, Mike; Proschan, Michael; Read, Sarah; Santos, Michael (FNIH) [T]; Shen, Yuan Li (FDA/CDER); Stein, Peter (FDA/CDER); Wholley, David (FNIH) [T]; Buchman, Tim (OS/ASPR/BARDA) (CTR); Collins, Sylva (FDA/CDER); Amanda Peppercorn; Garner, Carl; Higgs, Elizabeth (NIH/NIAID) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Burgess, Timothy; Reineck, Lora (NIH/NHLBI) [E]; Aggarwal, Neil (NIH/NHLBI) [E]; Rosenberg, Yves (NIH/NHLBI) [E]; Goff, David (NIH/NHLBI) [E] ((b) (6)); Brown, Jeremy (NIH/NINDS) [E]; Gadbois, Ellen (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]; Jacqueline Kirchner

Optional Attendees: Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Young, John; Biggs, Mary; Butcher, Tina; Demarcus; Macone, Erin; Melencio, Cheryl (FNIH) [T]; Salathin, Carla; Tountas, Karen (FNIH) [T]; Menetski, Joseph (FNIH) [T]; James, Stephanie (FNIH) [T]; Wachtel, Jonathan; Tolman, Brett; Alvarez, Rosa; Gonzalez, Nina; Dana Carluccio; Rose Li Central Account; Anderson, Margaret; Lucas Smalldon; Stratton, Benjamin; (b) (6) Mollica, Linda /US; Qashu, Felicia (NIH/OD) [E]; Patterson, Amy

Dear ACTIV TX-Clinical WG,

Please find attached the slides for tomorrow's meeting which contain the agenda. We will be using this meeting as last week to update on the progress of the master protocol groups and the mAb subteam from the Agent Prioritization group.

Please let us know if there is anything else you feel the team needs to discuss.

Thanks,
Stacey

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 (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Colvis, Christine
 (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hewitt, Judith (NIH/NIAID) [E]
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcbd42cbb4014d9b26af30cc-jhewitt]; Deming, Damon (FDA/CDER)
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda]; Parker, Ashley
 (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Adams, Peter
 (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; Qashu, Felicia (NIH/OD)
 [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Punturieri, Antonello
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 (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7fa2baf951848b5bf1f76a049a0eca6-charettemf]; Fessel, Josh (NIH/NHLBI)
 [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=294e2bb481d94b83a1917f15338dfe19-fesseljp]; Menetski, Joseph (FNIH) [T]
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Hild, Sheri (NIH/OD) [E]
 (b) (6) (b) (6) (b) (6) (b) (6)
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 [(b) (6) (b) (6) Ottinger, Elizabeth (NIH/NCATS) [E]
 (b) (6) ; Colvis, Christine (NIH/NCATS) [E] [(b) (6) Hewitt, Judith (NIH/NIAID) [E]
 (b) (6) Deming, Damon (FDA/CDER) [(b) (6) (b) (6)
 (b) (6) (b) (6) Parker, Ashley (NIH/OD) [E] [(b) (6) Collins, Francis
 (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf];
 (b) (6) ; Rao, Srinivas (b) (6) ; Qashu, Felicia (NIH/OD) [E]
 [(b) (6)]; Tomas Cihlar [(b) (6) Pitt, Margaret L CIV USARMY MEDCOM
 USAMRIID (USA) [(b) (6) Punturieri, Antonello (NIH/NHLBI) [E] [(b) (6)];
 Charette, Marc (NIH/NHLBI) [E] [(b) (6) Fessel, Josh (NIH/NHLBI) [E] [(b) (6)]; Adams,
 Peter (OS/ASPR/BARDA) [(b) (6)]; (b) (6)
CC: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcd28414883d0b6996d677257-wholleyd]; Austin, Christopher
 (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabcd2247548e596778304f781f-austinc]; Melencio, Cheryl (FNIH) [T]
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 (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI)
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID)
 [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Tountas, Karen (FNIH) [T]
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Santos, Michael (FNIH) [T]
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Adam, Stacey (FNIH) [T]
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; James, Stephanie (FNIH) [T]

[/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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 (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; Florence, Clint (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Nancy Haigwood [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=03d589f440d84691ac0a530e4ba6ceb5-haigwoon.oh]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Wholley, David (FNIH) [T] [(b) (6)]; Melencio, Cheryl (FNIH) [T] [(b) (6) Colvis, Christine (NIH/NCATS) [E] [(b) (6) Desrosiers, Betsy [(b) (6) Jansen, Kathrin [(b) (6) Kurilla, Michael (NIH/NCATS) [E] [(b) (6) Lowy, Douglas (NCI) [(b) (6) Read, Sarah (NIH/NIAID) [E] [(b) (6) Tountas, Karen (FNIH) [T] [(b) (6) Santos, Michael (FNIH) [T] [(b) (6) Adam, Stacey (FNIH) [T] [(b) (6) James, Stephanie (FNIH) [T] [(b) (6) Alvarez, Rosa Maria [(b) (6) Kim, Elizabeth [(b) (6) Tolman, Brett [(b) (6) Wachtel, Jonathan [(b) (6) Prabhavathi Fernandes [(b) (6) Rose Li [(b) (6) Dana Carluccio [(b) (6) Lagos, Enrique (NIH/NCATS) [E] [(b) (6) Jonson, Samantha (NIH/NCATS) [E] [(b) (6) Gonzalez, Nina [(b) (6) Simon, Dina (NIH/OD) [C] [(b) (6) Burrus-Shaw, Cyndi (NIH/OD) [E] [(b) (6) Dave Frankowski [(b) (6) Baric, Toni C [(b) (6) Lowy, Douglas (NIH/NCI) [E] [(b) (6) Florence, Clint (NIH/NIAID) [E] [(b) (6)]; Nancy Haigwood [(b) (6) Stratton, Benjamin [(b) (6) Gadbois, Ellen (NIH/OD) [E] [(b) (6) Rodriguez, Robin D [(b) (6) Austin, Christopher (NIH/NCATS) [E] [(b) (6) Hughes, Eric [(b) (6) Anderson, James (NIH/OD) [E] [(b) (6) Diamond, Michael [(b) (6)

Start: 7/29/2020 2:00:00 PM
End: 7/29/2020 3:00:00 PM

Recurrence: (none)

Required Attendees: Menetski, Joseph (FNIH) [T]; Hild, Sheri (NIH/OD) [E]; (b) (6) (b) (6)
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 (b) (6) Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E];
 (b) (6) Rao, Srinivas; Qashu, Felicia (NIH/OD) [E]; Tomas Cihlar; Pitt, Margaret L CIV
 USARMY MEDCOM USAMRIID (USA); Punturieri, Antonello (NIH/NHLBI) [E]; Charette, Marc (NIH/NHLBI) [E]; Fessel,
 Josh (NIH/NHLBI) [E]; Adams, Peter (OS/ASPR/BARDA); (b) (6)
Optional Attendees: Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Jansen,
 Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH)
 [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim,
 Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Rose Li; Dana Carluccio; Lagos, Enrique
 (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi
 (NIH/OD) [E]; Dave Frankowski; Baric, Toni C; Lowy, Douglas (NIH/NCI) [E]; Florence, Clint (NIH/NIAID) [E]; Nancy

Haigwood; Stratton, Benjamin; Gadbois, Ellen (NIH/OD) [E]; Diamond, Michael; Nancy Haigwood; Rodriguez, Robin D; Austin, Christopher (NIH/NCATS) [E]; Hughes, Eric; Anderson, James (NIH/OD) [E]

To: Bozzette, Sam (NIH/NCATS) [E] [(b) (6)]; De Claro, R. Angelo (FDA/CDER) [(b) (6)]; Eric Hughes [(b) (6)]; Judy Currier [(b) (6)]; Mellors, John W [(b) (6)]; Parker, Ashley (NIH/OD) [E] [(b) (6)]; Proschan, Michael (NIH/NIAID) [E] [(b) (6)]; Read, Sarah (NIH/NIAID) [E] [(b) (6)]; Santos, Michael (FNIH) [T] [(b) (6)]; Shen, Yuan Li (FDA/CDER) [(b) (6)]; Stein, Peter (FDA/CDER) [(b) (6)]; Wholley, David (FNIH) [T] [(b) (6)]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [(b) (6)]; Collins, Sylva (FDA/CDER) [Sylva. (b) (6)]; Higgs, Elizabeth (NIH/NIAID) [E] [(b) (6)]; Koroshetz, Walter (NIH/NINDS) [E] [(b) (6)]; Timothy Burgess [(b) (6)]; Reineck, Lora (NIH/NHLBI) [E] [(b) (6)]; Aggarwal, Neil (NIH/NHLBI) [E] [(b) (6)]; Rosenberg, Yves (NIH/NHLBI) [E] [(b) (6)]; Goff, David (NIH/NHLBI) [E] [(b) (6)]; Brown, Jeremy (NIH/NINDS) [E] [(b) (6)]; Culp, Michelle (NIH/OD) [E] [(b) (6)]; Beigel, John (NIH) [E] [(b) (6)]; Sizemore, Christine (NIH/FIC) [E] [(b) (6)]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Draghia-Akli, Ruxandra [(b) (6)]; Gottesdiener, Keith [(b) (6)]; Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Kim, Elizabeth [(b) (6)]; LaVange, Lisa [(b) (6)]; Levy, Elliot [(b) (6)]; Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Menon, Sandeep [(b) (6)]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Patel, Naimish [(b) (6)]; Peppercorn, Amanda [(b) (6)]; Poole, Mike [(b) (6)]; Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Collins, Sylva (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylva.Coli]; Amanda Peppercorn [(b) (6)]; Garner, Carl [(b) (6)]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetz]; Timothy Burgess [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=52e5e03dcbc847709eaab64457efa57e-TimothyBurg]; Reineck, Lora (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a62d88ba0c3b44e3bb922236c61304b3-reineckla]; Aggarwal, Neil (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c9de6615504ff9889f3b0c44a63526-aggarwalnr]; Rosenberg, Yves (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a5cb3e9a3a2747c38c42f68f5c8e40cf-roosenbey]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Brown, Jeremy (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce971eefec944a68a94add3b24835f5-brownj7]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Jacqueline Kirchner [(b) (6) Beigel, John (NIH) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=492ae062f7d74e3cbd894e30160869f0-jbeigel]; Phillips, L Revell CIV DTRA RD (USA) [(b) (6) Petrovick, Martha - 0449 - MITLL [(b) (6) Sizemore, Christine (NIH/FIC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=05494833e0fc47a9acac194cd338b201-csizemore]; Larry Tsai [(b) (6) Wung, Peter K [(b) (6) Colvis, Christine (NIH/NCATS) [E] [(b) (6)]; Lowy, Douglas (NCI) [(b) (6) Melencio, Cheryl (FNIH) [T] [(b) (6) Menetski, Joseph (FNIH) [T] [(b) (6) Qashu, Felicia (NIH/OD) [E] [(b) (6)]; Patterson, Amy (NIH/NHLBI) [E] [(b) (6)]; Rubin, Daniel B. (FDA/CDER) [(b) (6) Marston, Hilary (NIH/NIAID) [E] [(b) (6) Chen, Helen Q. [(b) (6) Hoots, W. Keith (NIH/NHLBI) [E] [(b) (6)]; Groesch, Mary (NIH/NHLBI) [E] [(b) (6) Shipp, Allan (NIH/NHLBI) [E] [allan. (b) (6) Kindzelski, Andrei (NIH/NHLBI) [E] [(b) (6) Walker, Paula (NIH/NINDS) [E] [(b) (6) Sorosa, Alex David [(b) (6) Lumsden, Joanne (NIH/NCATS) [C] [(b) (6)]; Lerner, Andrea (NIH/NIAID) [E] [(b) (6) Embry, Alan (NIH/NIAID) [E] [(b) (6) Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Jansen, Kathrin [(b) (6) Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Young, John [(b) (6) Biggs, Mary [(b) (6) Butcher, Tina [(b) (6) Demarcus [(b) (6) Macone, Erin [(b) (6) Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Salathin, Carla [(b) (6) Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Dana Carluccio [(b) (6) Rose Li Central Account [(b) (6) Lucas Smalldon [(b) (6) Mollica, Linda /US [(b) (6) Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Marston, Hilary (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab30660917b942ffba9ae95d631116f3-marstonhd]; Chen, Helen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8801b022ef974bf7bda8fd06f67002cf-qingchen.de]; Hoots, W. Keith (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=328221d5416d4fc59262c6c2eca59d4c-hootswk]; Groesch, Mary (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=69ab77a4c9bf499383186b9d9870344e-groeschm]; Shipp, Allan (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=16001e8ab49c4489aef107bd0ce27715-shippa]; Kindzelski, Andrei (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8bda5194bdca4d2594626f6313d2db5c-kindzelskia]; Hone, David M (Dave) CIV DTRA J9 (USA) [(b) (6) Reisler, Ronald B CTR USARMY DOD JPEO CBRND (USA) [(b) (6) Walker, Paula (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

From: Tountas, Karen (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=40C04FEF6F1E46F5B750753CD5A14F93-TOUNTASKH]
Sent: 6/25/2020 1:38:13 PM
To: Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Bascles, Lionel [(b) (6)]; Cohen, Myron [(b) (6)]; Corey, Larry [(b) (6)]; Victoria Davey [(b) (6)]; Desrosiers, Betsy [(b) (6)]; Dickens, Jim (NIH/NCATS) [C] [(b) (6)]; Doroshow, James (NIH/NCI) [E] [(b) (6)]; Garner, Carlos [(b) (6)]; Goff, David (NIH/NHLBI) [E] [(b) (6)]; Kurilla, Michael (NIH/NCATS) [E] [(b) (6)]; Mensah, George (NIH/NHLBI) [E] [(b) (6)]; Nayak, Seema (NIH/NIAID) [E] [(b) (6)]; Payton, Manizhe (NIH/NIAID) [E] [(b) (6)]; Resnansky, Laura [(b) (6)]; Sizemore, Christine (NIH/FIC) [E] [(b) (6)]; Stein, Peter (FDA/CDER) [(b) (6)]; Takas, Therese [the (b) (6)]; Vincent, Mike [(b) (6)]; Weinmann, Gail (NIH/NHLBI) [E] [(b) (6)]; Srinivasan, Badhri [(b) (6)]
CC: Wachtel, Jonathan [(b) (6)]; Colvis, Christine (NIH/NCATS) [E] [(b) (6)]; Eric Hughes [(b) (6)]; Jansen, Kathrin [(b) (6)]; Lowy, Douglas (NCI) [(b) (6)]; Read, Sarah (NIH/NIAID) [E] [(b) (6)]; Young, John [(b) (6)]; Ardiffe, Bernadette [(b) (6)]; Criffield, Robin [(b) (6)]; Hamilton, Nancy [(b) (6)]; Melencio, Cheryl (FNIH) [T] [(b) (6)]; Minnich, Beth [bminn (b) (6)]; Mueller-Reichenstein, Petra [(b) (6)]; Pico, Dianna (NIH/NHLBI) [C] [(b) (6)]; Quadros, Nora [Nora. (b) (6)]; Katz, Rebecca (NIH/NCATS) [E] [(b) (6)]; Hill, Zoe (NIH/NHLBI) [C] [zoe.hill@nih.gov]; Adam, Stacey (FNIH) [T] [(b) (6)]; Anderson, Margaret [(b) (6)]; Parker, Ashley (NIH/OD) [E] [(b) (6)]; Carluccio, Dana [(b) (6)]; Culp, Michelle (NIH/OD) [E] [(b) (6)]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadbois]; Gonzalez, Nina [(b) (6)]; Heaton, Penny [penny. (b) (6)]; James, Stephanie (FNIH) [T] [(b) (6)]; Kenny, Dermot [(b) (6)]; Kublin, James [jkub (b) (6)]; Li, Rose [(b) (6)]; Menetski, Joseph (FNIH) [T] [(b) (6)]; Qashu, Felicia (NIH/OD) [E] [(b) (6)]; Santos, Michael (FNIH) [T] [(b) (6)]; Tuveson, Nancy [(b) (6)]; Wholley, David (FNIH) [T] [dwhol (b) (6)]; Bethany Stokes [(b) (6)]; Collins, Francis (NIH/OD) [E] [(b) (6)]; Wood, Gretchen (NIH/OD) [E] [(b) (6)]
Subject: ACTIV Clinical Trial Capacity Working Group - reporting meeting
Attachments: Clinical Trial Capacity Working Group Meeting Agenda_07282020.pdf
Location: https://fnih.zoom.us/ (b) (6)
Start: 7/28/2020 1:00:00 PM
End: 7/28/2020 2:00:00 PM
Show Time As: Tentative

Required Attendees: Bascles, Lionel; Cohen, Myron; Corey, Larry; Davey, Victoria; Desrosiers, Betsy; Dickens, Jim (NIH/NCATS) [C]; Doroshow, James (NIH/NCI) [E]; Garner, Carlos; Goff, David (NIH/NHLBI) [E]; Kurilla, Mike; Mensah, George; Nayak, Seema (NIH/NIAID) [E]; Payton, Manzine; Resnansky, Laura; Sizemore, Christine (NIH/FIC) [E]; Srinivasan, Badhri; Stein, Peter (FDA/CDER); Takas, Therese; Vincent, Mike; Weinmann, Gail
Optional Attendees: Wachtel, Jonathan; Colvis, Christine (NIH/NCATS) [E]; Hughes, Eric; Jansen, Kathrin; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Young, John; Ardiffe, Bernadette; Criffield, Robin; Hamilton, Nancy; Melencio, Cheryl (FNIH) [T]; Minnich, Beth; Mueller-Reichenstein, Petra; Pico, Dianna; Quadros, Nora; Rebecca (NIH/NCATS) Katz [E] [(b) (6)]; Zoe (NIH/NHLBI) Hill [C] [(b) (6)]; Adam, Stacey (FNIH) [T]; Anderson, Margaret; Ashley (NIH/OD) Parker [E] [(b) (6)]; Carluccio, Dana; Culp, Michelle (NIH/OD) [E]; Gadbois, Ellen (NIH/OD) [E]; Gonzalez, Nina; Heaton, Penny; James, Stephanie; Kenny, Dermot; Kublin, James; Li, Rose; Menetski, Joseph (FNIH) [T]; Qashu, Felicia; Santos, Michael (FNIH); Tuveson, Nancy; Wholley, David (FNIH) [T]; Bethany Stokes; Collins, Francis (NIH/OD) [E]; Wood, Gretchen (NIH/OD) [E]

Dear Colleagues, Attached, please find the agenda for this last meeting of the Clinical Trial Capacity Working Group. With best regards, Karen

Dear Clinical Trial Capacity Working group members - As the tiger teams continue to work closely with ACTIV protocol development and operations teams, and the 'playbook' development teams ramp up to quickly develop these resources, we will reduce the number of times the full WG meets in July to every other week (July 14th and 28th). Best, Karen

Karen Tountas is inviting you to a scheduled Zoom meeting.

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From: Appell, Evan [(b) (6)]
Sent: 11/12/2020 7:27:37 PM
To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Draghia-Akli, Ruxandra [(b) (6)]; Eisner, Mark [(b) (6)]; Gottesdiener, Keith [(b) (6)]; Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Kim, Elizabeth [(b) (6)]; LaVange, Lisa [(b) (6)]; Levy, Elliot [(b) (6)]; Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Menon, Sandeep [(b) (6)]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Patel, Naimish [(b) (6)]; Peppercorn, Amanda [(b) (6)]; Poole, Mike [(b) (6)]; Proshan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcd28414883d0b6996d677257-wholleyd]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Collins, Sylvia (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylvia.Collis]; Amanda Peppercorn [(b) (6)]; Garner, Carl [(b) (6)]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96c8ca9-ehiggs]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Timothy Burgess [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=52e5e03dcbc847709eaab64457efa57e-TimothyBurg]; Reineck, Lora (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a62d88ba0c3b44e3bb922236c61304b3-reineckla]; Aggarwal, Neil (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c9de6615504ff9889f3b0c44a63526-aggarwalnr]; Rosenberg, Yves (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a5cb3e9a3a2747c38c42f68f5c8e40cf-rosenbey]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Brown, Jeremy (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce971eefec944a68a94add3b24835f5-brownj7]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Jacqueline Kirchner

[(b) (6) Beigel, John (NIH) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=492ae062f7d74e3cbd894e30160869f0-jbeigel]; Phillips, L Revell CIV DTRA RD (USA) [(b) (6) Petrovick, Martha - 0449 - MITLL [(b) (6) Sizemore, Christine (NIH/FIC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=05494833e0fc47a9acac194cd338b201-csizemore]

CC: Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy [(b) (6) Jansen, Kathrin [(b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Young, John [(b) (6) Biggs, Mary [(b) (6) Butcher, Tina [(b) (6) Demarcus [(b) (6) Macone, Erin [(b) (6) Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Salathin, Carla [(b) (6) Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Wachtel, Jonathan [(b) (6) btolman [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user7b137a1e]; Alvarez, Rosa Maria [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user706e5647]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Dana Carluccio [(b) (6) Rose Li Central Account [(b) (6) Margaret Anderson [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab9a138f1e284c689fedfb10b8cc5295-marganderso]; Lucas Smalldon [(b) (6) Stratton, Benjamin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=usere3ed7188]; [(b) (6) Mollica, Linda /US [(b) (6) Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Marston, Hilary (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab30660917b942ffb9ae95d631116f3-marstonhd]; Chen, Helen Q. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user34aa917e]; Wung, Peter /US [(b) (6) Hoots, W. Keith (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=328221d5416d4fc59262c6c2eca59d4c-hootswk]; Groesch, Mary (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=69ab77a4c9bf499383186b9d9870344e-groeschm]; Shipp, Allan (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=16001e8ab49c4489aef107bd0ce27715-shippa]; Kindzelski, Andrei (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8bda5194bdca4d2594626f6313d2db5c-kindzelskia]; Hone, David M (Dave) CIV DTRA J9 (USA) [(b) (6) Reisler, Ronald B CTR USARMY DOD JPEO CBRND (USA) [(b) (6) Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Elsaid, Olivia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userf0efa7bd]

Subject: RE: ACTIV Therapeutics-Clinical Working Group Meeting

Attachments: ACTIV_TX-Clinical_Working Group Meeting Guide_20201112_vF.pdf

Hi All,

Thank you for joining our Therapeutics-Clinical Working Group meeting this afternoon. Please see attached for the materials we reviewed during our call, and let us know if you have any questions or feedback.

Best,
Evan

Evan Appell

Deloitte Consulting LLP

Mobile: + (b) (6)

(b) (6)

-----Original Appointment-----

From: Adam, Stacey (FNIH) [T] < (b) (6) >

Sent: Monday, August 31, 2020 10:34 AM

To: Adam, Stacey (FNIH) [T]; Appell, Evan; Bozzette, Sam (NIH/NCATS) [E]; Butterton, Joan; De Claro, R. Angelo (FDA/CDER); Draghia-Akli, Ruxandra; Eisner, Mark; Gottesdiener, Keith; Hughes, Eric; Judy Currier; Kim, Elizabeth; LaVange, Lisa; Levy, Elliot; Mellors, John W; Menon, Sandeep; Parker, Ashley (NIH/OD) [E]; Patel, Naimish; Peppercorn, Amanda; Poole, Mike; Proschan, Michael (NIH/NIAID) [E]; Read, Sarah (NIH/NIAID) [E]; Santos, Michael (FNIH) [T]; Shen, Yuan Li (FDA/CDER); Stein, Peter (FDA/CDER); Wholley, David (FNIH) [T]; Buchman, Tim (OS/ASPR/BARDA) (CTR); Collins, Sylva (FDA/CDER); Amanda Peppercorn; Garner, Carl; Higgs, Elizabeth (NIH/NIAID) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Timothy Burgess; Reineck, Lora (NIH/NHLBI) [E]; Aggarwal, Neil (NIH/NHLBI) [E]; Rosenberg, Yves (NIH/NHLBI) [E]; Goff, David (NIH/NHLBI) [E]; Brown, Jeremy (NIH/NINDS) [E]; Gadbois, Ellen (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]; Jacqueline Kirchner; Beigel, John (NIH) [E]; Phillips, L Revell CIV DTRA RD (USA); Petrovick, Martha - 0449 - MITLL;

(b) (6); Sizemore, Christine (NIH/FIC) [E]

Cc: Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Young, John; Biggs, Mary; Butcher, Tina; Demarcus; Macone, Erin; Melencio, Cheryl (FNIH) [T]; Salathin, Carla; Tountas, Karen (FNIH) [T]; Menetski, Joseph (FNIH) [T]; James, Stephanie (FNIH) [T]; Wachtel, Jonathan; Tolman, Brett; Alvarez, Rosa Maria; Gonzalez, Nina; Dana Carluccio; Rose Li Central Account; Anderson, Margaret; Lucas Smalldon; Stratton, Benjamin; (b) (6); Mollica, Linda /US; Qashu, Felicia (NIH/OD) [E]; Patterson, Amy (NIH/NHLBI) [E]; Rubin, Daniel B. (FDA/CDER); Marston, Hilary (NIH/NIAID) [E]; Chen, Helen Q.; Wung, Peter /US; Hoots, W. Keith (NIH/NHLBI) [E]; Groesch, Mary (NIH/NHLBI) [E]; Shipp, Allan (NIH/NHLBI) [E]; Kindzelski, Andrei (NIH/NHLBI) [E]; Hone, David M (Dave) CIV DTRA J9 (USA); Reisler, Ronald B CTR USARMY DOD JPEO CBRND (USA); Freire, Maria (FNIH) [T]; Elsaid, Olivia

Subject: ACTIV Therapeutics-Clinical Working Group Meeting

When: Thursday, November 12, 2020 1:00 PM-2:00 PM (UTC-05:00) Eastern Time (US & Canada).

Where: <https://fnih.zoom.us/j/9181212121> (b) (6)

-----Original Appointment-----

From: Adam, Stacey (FNIH) [T] < (b) (6) >

Sent: Wednesday, June 17, 2020 8:48 AM

To: Adam, Stacey (FNIH) [T]; Bozzette, Sam (NIH/NCATS) [E]; Butterton, Joan; De Claro, R. Angelo (FDA/CDER); Draghia-Akli, Ruxandra; Eisner, Mark; Gottesdiener, Keith; Hughes, Eric; Judy Currier; Kim, Elizabeth; LaVange, Lisa; Levy, Elliot; Mellors, John W; Menon, Sandeep; Parker, Ashley (NIH/OD) [E]; Patel, Naimish; Peppercorn, Amanda; Poole, Mike; Proschan, Michael (NIH/NIAID) [E]; Read, Sarah (NIH/NIAID) [E]; Santos, Michael (FNIH) [T]; Shen, Yuan Li (FDA/CDER); Stein, Peter (FDA/CDER); Wholley, David (FNIH) [T]; Buchman, Tim (OS/ASPR/BARDA) (CTR); Collins, Sylva (FDA/CDER); Amanda Peppercorn; Garner, Carl; Higgs, Elizabeth (NIH/NIAID) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Timothy Burgess; Reineck, Lora (NIH/NHLBI) [E]; Aggarwal, Neil (NIH/NHLBI) [E]; Rosenberg, Yves (NIH/NHLBI) [E]; Goff, David (NIH/NHLBI) [E]; Brown, Jeremy (NIH/NINDS) [E]; Gadbois, Ellen (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]; Jacqueline Kirchner; Beigel, John (NIH) [E]; Phillips, L Revell CIV DTRA RD (USA); Petrovick, Martha - 0449 - MITLL; (b) (6); Sizemore, Christine (NIH/FIC) [E]

Cc: Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Young, John; Biggs, Mary; Butcher, Tina; Demarcus; Macone, Erin; Melencio, Cheryl (FNIH) [T]; Salathin, Carla;

Tountas, Karen (FNIH) [T]; Menetski, Joseph (FNIH) [T]; James, Stephanie (FNIH) [T]; Wachtel, Jonathan; Tolman, Brett; Alvarez, Rosa Maria; Gonzalez, Nina; Dana Carluccio; Rose Li Central Account; Anderson, Margaret; Lucas Smalldon; Stratton, Benjamin; (b) (6) Mollica, Linda /US; Qashu, Felicia (NIH/OD) [E]; Patterson, Amy (NIH/NHLBI) [E]; Rubin, Daniel B. (FDA/CDER); Marston, Hilary (NIH/NIAID) [E]; Chen, Helen Q.; Wung, Peter /US; Hoots, W. Keith (NIH/NHLBI) [E]; Groesch, Mary (NIH/NHLBI) [E]; Shipp, Allan (NIH/NHLBI) [E]; Kindzelski, Andrei (NIH/NHLBI) [E]; Hone, David M (Dave) CIV DTRA J9 (USA); Reisler, Ronald B CTR USARMY DOD JPEO CBRND (USA); Freire, Maria (FNIH) [T]; Elsaid, Olivia

Subject: ACTIV Therapeutics-Clinical Working Group Meeting

When: Occurs every Thursday effective 6/25/2020 until 12/31/2020 from 1:00 PM to 2:00 PM Eastern Standard Time.

Where: <https://fnih.zoom.us> (b) (6)

Stacey Adam is inviting you to a scheduled Zoom meeting.

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From: Tountas, Karen (FNIH) [T] [/o=EXCHANGELABS/ou=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/cn=RECIPIENTS/cn=40C04FEF6F1E46F5B750753CD5A14F93-TOUNTASKH]
Sent: 7/31/2020 7:12:27 PM
To: Bascles, Lionel [(b) (6)] Cohen, Myron [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2141b9e28c1a421fb3c1c4f75dd4c457-myron_cohen]; Corey, Larry [(b) (6)]; Victoria Davey [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c8291f38ec342f895243c0617e115ec-victoria.da]; Desrosiers, Betsy [(b) (6)]; Dickens, Jim (NIH/NCATS) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12591c90404e46caba73079cf4a5e2ea-dickensj]; Doroshov, James (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a1d0fb9f055940c39b387cae2485faa6-doroshovj]; Garner, Carlos [(b) (6)]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Mensah, George (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=284d85649e634a0a91bb0b9aac84846c-mensahga]; Nayak, Seema (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=51d5ee6848004578b5bf9c808eca8f6f-nayaksu]; Payton, Manizhe (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=81d1c1824bfa438a94da81520a8bca90-paytonma]; Resnansky, Laura [(b) (6)]; Sizemore, Christine (NIH/FIC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=05494833e0fc47a9acac194cd338b201-csizemore]; Srinivasan, Badhri [(b) (6)]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Takas, Therese [(b) (6)]; Vincent, Mike [(b) (6)]; Weinmann, Gail (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f38a543b4021483ba67e42af1165dcad-weinmang]; Heaton, Penny [(b) (6)]
CC: Wachtel, Jonathan [(b) (6)]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Anderson, Margaret [(b) (6)]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Kenny, Dermot [(b) (6)]; Kublin, James [jkublin@fredhutch.org]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Woodcock, Janet (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebfcf48879f92169bd7644e29-Janet.Woodc]
Subject: ACTIV Innovation Playbooks for the COVID-19 clinical trial environment
Attachments: ACTIV Innovation Playbooks.zip

Dear Clinical Trial Capacity Working Group Members,

I am pleased to distribute final versions of the five ACTIV Innovation Playbooks (zip file attached).

- eCOA (Electronic Clinical Outcomes Assessments)
- eConsent
- Mobile Nursing
- Remote Source Data Verification (SDV)
- Site Training/Tools

These 'playbooks' are designed specifically to provide high-level guidance for conducting clinical trials in the COVID-19 environment. Each includes practical guidance, considerations, and recommendations, and may include links to useful websites; documents such as checklists, sample letters and meeting agendas, materials to conduct due diligence activities, procedure manuals, and more; and potential vendor lists, which may not be complete, but are meant as a place to start. The playbooks are provided to you as Microsoft Word documents rather than pdf so that you may easily open and save the imbedded materials to modify and use. Thank you to our academic, NIH, and pharma colleagues for the enormous amount of time and effort given to producing these playbooks and for sharing your knowledge and materials.

Also attached is an Innovations Quick Reference Guide that provides a brief introduction to many other virtual, digital, online technology solutions or innovations that are becoming increasingly relevant in the COVID-19 clinical trial environment. This is not meant to be a comprehensive list of solutions for clinical trials in general, rather these innovations may help with expeditious and efficient clinical trial execution in the COVID-19 environment. Again, thank you to those on the Innovations Sub-WG who put their heads together and came up with this list and the accompanying considerations.

Please share these resources with your teams.

With my very best regards,
Karen

Karen H. Tountas, PhD
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Subject: Summary and action items - CT Capacity WG meeting #14

Attachments: Clinical_Trial_Capacity_Working_Group_Meeting_14_Final.pdf

Dear Clinical Trial Capacity Working Group Members,

Attached is the summary and action items for meeting #14 (June 2, 2020) of the full working group. The next full working group meeting is scheduled for Tuesday, June 9 at 9 am eastern US time.

With best regards,
Karen

Karen H. Tountas, PhD

Scientific Program Manager

Foundation for the National Institutes of Health

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Kozlowski, Mary (NIH/NCI) [C] [(b) (6) Johnson, Maureen (NIH/NCI) [E]
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[austinsj@niaid.nih.gov]; (b) (6) Isabel Ramsey [(b) (6) Parker,
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[(b) (6) Molloy, Delia (DPH) [delia. (b) (6) Arvin, Ann [(b) (6)
Vivek Shinde [(b) (6) Young, John [(b) (6)

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(b) (6) (b) (6) Greg Glenn; (b) (6) Haynes,
Barton; (b) (6) (b) (6) Marks, Peter (FDA/CBER); Mascola, John (NIH/VRC) [E];
Messonnier, Nancy (CDC/DDID/NCIRD/OD); Nelson Michael; Offit, Paul; (b) (6) Seals, Jonathan
(OS/ASPR/BARDA); (b) (6) (b) (6); Tal Zaks
Optional Attendees: Tolman, Brett; (b) (6) Hopps, Markay; Kozlowski, Mary (NIH/NCI) [C]; Johnson, Maureen
(NIH/NCI) [E]; (b) (6) Jeneffer Haynes; (b) (6) (b) (6)
(b) (6) Austin, Sarah (NIH/NIAID) [E]; (b) (6) Isabel Ramsey; Parker,

Ashley (NIH/OD) [E]; Marston, Hilary (NIH/NIAID) [E]; Qashu, Felicia (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]; Gadbois, Ellen (NIH/OD) [E]; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Menetski, Joseph (FNIH) [T]; Adam, Stacey (FNIH) [T]; Tountas, Karen (FNIH) [T]; James, Stephanie (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Kurilla, Michael (NIH/NCATS) [E]; Read, Sarah (NIH/NIAID) [E]; Young, John; Paul Gillard; Hamilton, Holli (OS/ASPR/BARDA); Modjarrad, Kayvon CIV USARMY MEDCOM WRAIR (USA); Kathleen Neuzil; Schrag, Stephanie (CDC/DDID/NCIRD/DBD); Verani, Jennifer R. (CDC/DDID/NCIRD/DBD); Thornburg, Natalie (CDC/DDID/NCIRD/DVD); Gonzalez, Nina; Wachtel, Jonathan; Stratton, Benjamin; Anderson, Margaret; (b) (6); (b) (6) Bethany Stokes; Kathleen Callahan; Molloy, Delia (DPH); Ann Arvin; Vivek Shinde

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To: Garner, Carl [(b) (6)] Levy, Elliot [(b) (6)] Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Draghia-Akli, Ruxandra [(b) (6)] Gottesdiener, Keith [(b) (6)] Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Kim, Elizabeth [(b) (6)] LaVange, Lisa [(b) (6)] Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Menon, Sandeep [(b) (6)] Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Patel, Naimish [(b) (6)] Peppercorn, Amanda [(b) (6)] Poole, Mike [(b) (6)] Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Collins, Sylvia (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylvia.Collis]; Amanda Peppercorn [(b) (6)] Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Timothy Burgess [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=52e5e03dcbc847709eaab64457efa57e-TimothyBurg]; Reineck, Lora (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a62d88ba0c3b44e3bb922236c61304b3-reineckla]; Aggarwal, Neil (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c9de6615504ff9889f3b0c44a63526-aggarwalnr]; Rosenberg, Yves (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a5cb3e9a3a2747c38c42f68f5c8e40cf-roosenbey]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Brown, Jeremy (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce971eefec944a68a94add3b24835f5-brownj7]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Jacqueline Kirchner [(b) (6)] Beigel, John (NIH) [E] [/o=ExchangeLabs/ou=Exchange Administrative

Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=492ae062f7d74e3cbd894e30160869f0-jbeigel]; Phillips, L Revell CIV DTRA RD (USA) [(b) (6) Petrovick, Martha - 0449 - MITLL [(b) (6) (b) (6) Sizemore, Christine (NIH/FIC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=05494833e0fc47a9acac194cd338b201-csizemore]; Larry Tsai [(b) (6) Wung, Peter K [(b) (6) Lerner, Andrea (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=53254f4fb04e4bcbabe37940b4b41887-fennellyam]; Kelly Beazley [(b) (6) Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Jansen, Kathrin [(b) (6) Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Young, John (b) (6) Biggs, Mary [(b) (6) Butcher, Tina [(b) (6) Demarcus [(b) (6) Macone, Erin [(b) (6) Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Salathin, Carla [(b) (6) Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Dana Carluccio [(b) (6) Rose Li Central Account [(b) (6) Lucas Smalldon [(b) (6) Mollica, Linda /US (b) (6) Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Marston, Hilary (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab30660917b942ffba9ae95d631116f3-marstonhd]; Chen, Helen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8801b022ef974bf7bda8fd06f67002cf-qingchen.de]; Hoots, W. Keith (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=328221d5416d4fc59262c6c2eca59d4c-hootswk]; Groesch, Mary (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=69ab77a4c9bf499383186b9d9870344e-groeschm]; Shipp, Allan (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=16001e8ab49c4489aef107bd0ce27715-shippa]; Kindzelski, Andrei (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8bda5194bdca4d2594626f6313d2db5c-kindzelskia]; Hone, David M (Dave) CIV DTRA J9 (USA) (b) (6) Reisler, Ronald B CTR USARMY DOD JPEO CBRND (USA) [(b) (6) Walker, Paula (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fbe81b9b832e40acbf5fd03bcfd32930-walkerp1]; Sorosa, Alex [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a221a6336336466793cff9145b09d91b-Contact_f12]; Lumsden, Joanne (NIH/NCATS) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1be900c2388d41f48e3f2cbcb2fed349-lumsdenjm]; Embry, Alan (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=882a18a10a134c49acac21cb83fd599d-embrya]; Dally, Nicolle [(b) (6)

Subject: ACTIV Therapeutics-Clinical Working Group

Attachments: ACTIV_TX-Clinical WG Meeting_20210304.pdf

Location: <https://fnih.zoom.> (b) (6)

Start: 3/4/2021 6:00:00 PM

End: 3/4/2021 7:00:00 PM

Show Time As: Tentative

Recurrence: Weekly

every Thursday from 1:00 PM to 2:00 PM

Required Attendees: Garner, Carl; Levy, Elliot; Bozzette, Sam (NIH/NCATS) [E]; Butterson, Joan; De Claro, R. Angelo (FDA/CDER); Draghia-Akli, Ruxandra; Gottesdiener, Keith; Hughes, Eric; Judy Currier; Kim, Elizabeth; LaVange, Lisa; Mellors, John; Menon, Sandeep; Parker, Ashley (NIH/OD) [E]; Patel, Naimish; Peppercorn, Amanda; Poole, Mike; Proschan, Michael; Read, Sarah; Santos, Michael (FNIH) [T]; Shen, Yuan Li (FDA/CDER); Stein, Peter (FDA/CDER); Wholley, David (FNIH) [T]; Buchman, Tim (OS/ASPR/BARDA) (CTR); Collins, Sylva (FDA/CDER); Amanda Peppercorn; Higgs, Elizabeth (NIH/NIAID) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Burgess, Timothy; Reineck, Lora (NIH/NHLBI) [E]; Aggarwal, Neil (NIH/NHLBI) [E]; Rosenberg, Yves (NIH/NHLBI) [E]; Goff, David (NIH/NHLBI) [E] (b) (6) Brown, Jeremy (NIH/NINDS) [E]; Gadbois, Ellen (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]; Jacqueline Kirchner; Beigel, John (NIH) [E]; Phillips, L Revell CIV DTRA RD (USA); Petrovick, Martha - 0449 - MITLL; (b) (6); Sizemore, Christine (NIH/FIC) [E]; Larry Tsai; Wung, Peter K

Optional Attendees: Lerner, Andrea (NIH/NIAID) [E]; Kelly Beazley; Colvis, Christine (NIH/NCATS) [E]; Jansen, Kathrin; Lowy, Douglas (NCI); Young, John; Biggs, Mary; Butcher, Tina; Demarcus; Macone, Erin; Melencio, Cheryl (FNIH) [T]; Salathin, Carla; Menetski, Joseph (FNIH) [T]; Dana Carluccio; Rose Li Central Account; Lucas Smalldon; (b) (6) Mollica, Linda /US; Qashu, Felicia (NIH/OD) [E]; Patterson, Amy (NIH/NHLBI) [E]; Rubin, Daniel B. (FDA/CDER); Marston, Hilary (NIH/NIAID) [E]; Chen, Helen Q.; Hoots, W. Keith (NIH/NHLBI) [E]; Groesch, Mary (NIH/NHLBI) [E]; Shipp, Allan (NIH/NHLBI) [E]; Kindzelski, Andrei (NIH/NHLBI) [E]; Hone, David M (Dave) CIV DTRA J9 (USA); Reisler, Ronald B CTR USARMY DOD JPEO CBRND (USA); Walker, Paula (NIH/NINDS) [E]; Sorosa, Alex David; Lumsden, Joanne (NIH/NCATS) [C]; Embry, Alan (NIH/NIAID) [E]; Dally, Nicolle

Dear ACTIV TX-Clinical WG,

Please find attached the slides for today's meeting.

Thanks,
Stacey

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From: Menetski, Joseph (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5001AF52DC4A427EA3D34F1E072F8CB7-MENETSKIJP]
Sent: 10/20/2020 5:16:48 PM
To: (b) (6) (b) (6) Hild, Sheri (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=edd7f1939fb94be3bf063f925ac15f02-hildsa]; (b) (6) (b) (6) (b) (6) (b) (6)
(b) (6) Baric, Ralph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.email]; (b) (6) Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcb42cbb4014d9b26af30cc-jhewitt]; Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda]; (b) (6) (b) (6) (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; ken.duncan@gatesfoundation.org; Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; Rao, Srinivas [(b) (6) Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Tomas Cihlar [(b) (6) Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA) [(b) (6) Punturieri, Antonello (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ca7f3106e5f24b5cb5e933c6ee7a6bc7-punturiera]; Charette, Marc (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7fa2baf951848b5bf1f76a049a0eca6-charettemf]; Fessel, Josh (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=294e2bb481d94b83a1917f15338dfe19-fesseljp]; I (b) (6)
CC: (b) (6) (b) (6) Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy [(b) (6) Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Jansen, Kathrin [(b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Alvarez, Rosa Maria

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user706e5647]; Kim, Elizabeth [(b) (6) btolman [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user7b137a1e]; Wachtel, Jonathan (b) (6) Prabhavathi Fernandes [(b) (6) Diamond, Michael [(b) (6) Rose Li [(b) (6) Dana Carluccio [dana. (b) (6) Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagoses]; Jonson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Rodriguez, Robin D [(b) (6) Dave Frankowski [david. (b) (6) Baric, Toni C [(b) (6) Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; Florence, Clint (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Nancy Haigwood [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=03d589f440d84691ac0a530e4ba6ceb5-haigwoon.oh]; Stratton, Benjamin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=usere3ed7188]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Hawk, Harrison [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user280c84f8]; Mason, Stephen [(b) (6) Connelly, Sarah [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3ed93bab]

Subject: ACTIV Preclinical full working group

Location: https://fnih.zoom.us/ (b) (6)

Start: 10/21/2020 2:15:00 PM

End: 10/21/2020 3:00:00 PM

Show Time As: Tentative

Recurrence: Weekly
every Wednesday from 10:00 AM to 11:00 AM

Required Attendees: (b) (6) (b) (6) Hild, Sheri (NIH/OD) [E]; (b) (6)
(b) (6) (b) (6) (b) (6) (b) (6)
(b) (6) (b) (6) (b) (6) (b) (6)
(b) (6) (b) (6) (b) (6) (b) (6)
(b) (6) Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E];
(b) (6) Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas; Qashu, Felicia (NIH/OD) [E];
Tomas Cihlar; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA); Punturieri, Antonello (NIH/NHLBI) [E];
Charette, Marc (NIH/NHLBI) [E]; Fessel, Josh (NIH/NHLBI) [E]; (b) (6)

Optional Attendees: (b) (6) (b) (6) Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Diamond, Michael; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski; Baric, Toni C; Lowy, Douglas (NIH/NCI) [E]; Florence, Clint (NIH/NIAID) [E]; Nancy Haigwood; Stratton, Benjamin; Gadbois, Ellen (NIH/OD) [E]; Anderson, James (NIH/OD) [E]; Hawk, Harrison; Mason, Stephen; Connelly, Sarah

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Joseph Menetski is inviting you to a scheduled Zoom meeting.

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From: Culp, Michelle (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4E38FA37E0424217AA0A283CBA9E5098-MCULP]
Sent: 7/20/2020 7:34:39 PM
To: Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]
Subject: RE: did you get an invite for the July 15 Exec Comm meeting?

Ellen,

Oh, no. Yes, I had the invitation and was on the call. The next big call will be the Leadership call on 7/29. I have the meeting invitation. I hope you have it, too.

-Michelle

From: Gadbois, Ellen (NIH/OD) [E] <(b) (6)>
Sent: Monday, July 20, 2020 2:43 PM
To: Culp, Michelle (NIH/OD) [E] <(b) (6)>
Subject: did you get an invite for the July 15 Exec Comm meeting?

Hi Michelle,

It dawned on me too late that I didn't have the July 15 ACTIV Executive Committee Teleconference on my calendar. I got the slides from David in the email below, but I don't think I ever got the invitation. Did you get the invitation? I shouldn't miss the next one.

Thanks,
Ellen

From: Melencio, Cheryl (FNIH) [T] <(b) (6)> **On Behalf Of** Wholley, David (FNIH) [T]
Sent: Tuesday, July 14, 2020 8:44 PM
To: Collins, Francis (NIH/OD) [E] <(b) (6)>; Disbrow, Gary (OS/ASPR/BARDA) <(b) (6)>; Dolsten, Mikael <(b) (6)>; Fauci, Anthony (NIH/NIAID) [E] <(b) (6)>; Gibbons, Gary (NIH/NHLBI) [E] <(b) (6)>; Marks, Peter (FDA/CBER) <(b) (6)>; Pao, William <(b) (6)>; Pamp, Andrew <(b) (6)>; Stoffels, Paul <(b) (6)>; Woodcock, Janet (FDA/CDER) <(b) (6)>; Colvis, Christine (NIH/NCATS) [E] <(b) (6)>; Desrosiers, Betsy <(b) (6)>; Eric Hughes <eric.hughes@novartis.com>; Jansen, Kathrin <(b) (6)>; Kurilla, Michael (NIH/NCATS) [E] <(b) (6)>; Lowy, Douglas (NCI) <(b) (6)>; Read, Sarah (NIH/NIAID) [E] <(b) (6)>; Young, John <(b) (6)>
Cc: Anderson, James (NIH/OD) [E] <(b) (6)>; Austin, Christopher (NIH/NCATS) [E] <(b) (6)>; Burklow, John (NIH/OD) [E] <(b) (6)>; Castillejos, Carlos <(b) (6)>; Culp, Michelle (NIH/OD) [E] <(b) (6)>; FNIH Central Account <(b) (6)>; Freire, Maria (FNIH) [T] <(b) (6)>; Gadbois, Ellen (NIH/OD) [E] <(b) (6)>; Hallett, Adrienne (NIH/OD) [E] <(b) (6)>; Lane, Cliff (NIH/NIAID) [E] <(b) (6)>; Myles, Renate (NIH/OD) [E] <(b) (6)>; Parker, Ashley (NIH/OD) [E] <(b) (6)>; Tabak, Lawrence (NIH/OD) [E] <(b) (6)>; Wolinetz, Carrie (NIH/OD) [E] <(b) (6)>; Adam, Stacey (FNIH) [T] <(b) (6)>; Alvarez, Rosa <(b) (6)>; Anderson, Margaret <(b) (6)>; Chen, Helen <(b) (6)>; Elsaid, Olivia <(b) (6)>; Gonzalez, Nina <(b) (6)>; James, Stephanie (FNIH) [T] <(b) (6)>; Menetski, Joseph (FNIH) [T] <(b) (6)>; Santos, Michael (FNIH) [T] <(b) (6)>; Stratton, Ben <(b) (6)>; Tolman, Brett <(b) (6)>; Tountas, Karen (FNIH) [T] <(b) (6)>; Wachtel, Jonathan <(b) (6)>; Wholley, David (FNIH) [T] <(b) (6)>; Gorman, Greta (FNIH) [T] <(b) (6)>

(b) (6) >; Meltzer, Abbey (FNIH) [T] < (b) (6) Melencio, Cheryl (FNIH) [T]
< (b) (6)

Subject: Materials for July 15 ACTIV Executive Committee Teleconference

Dear ACTIV EC members, Working Group Co-Chairs, and meeting participants:

Please see attached the PowerPoint slides, including the agenda, for our meeting (via Zoom) from 3:00 PM to 4:30 PM Eastern U.S. time tomorrow, Wednesday July 15. I have also attached notes from our July 1 Leadership Team meeting as well as our last EC meeting on June 17.

The Zoom meeting information is:

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Please let Joe Menetski or Cheryl Melencio here at FNIH (copied) know if you are having any problems connecting. I look forward to a productive meeting.

Regards,

David

David Wholley
Senior Vice-President, Research Partnerships
Foundation for the National Institutes of Health

(b) (6)

fnih.org

11400 Rockville Pike Suite 600 North Bethesda, MD 20852

In 2019, the FNIH earned the highest rating from Charity Navigator for the fifth consecutive year and was recognized as an organization that exceeds industry standards.

To: Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Hild, Sheri (NIH/OD) [E] [(b) (6)]; (b) (6) (b) (6) (b) (6) (b) (6) (b) (6) Baric, Ralph [(b) (6) (b) (6) Ottinger, Elizabeth (NIH/NCATS) [E] [(b) (6) Colvis, Christine (NIH/NCATS) [E] [(b) (6) Hewitt, Judith (NIH/NIAID) [E] (b) (6) Deming, Damon (FDA/CDER) | (b) (6) (b) (6) (b) (6) Parker, Ashley (NIH/OD) [E] [(b) (6) Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; (b) (6) Adams, Peter (OS/ASPR/BARDA) [(b) (6)]; Rao, Srinivas [(b) (6) Qashu, Felicia (NIH/OD) [E] [(b) (6) Tomas Cihlar [(b) (6) Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA) [(b) (6) Punturieri, Antonello (NIH/NHLBI) [E] [(b) (6) Charette, Marc (NIH/NHLBI) [E] [(b) (6) Fessel, Josh (NIH/NHLBI) [E] (b) (6)]; (b) (6) (b) (6) Wholley, David (FNIH) [T] (b) (6) Austin, Christopher (NIH/NCATS) [E] [(b) (6) .gov]; Melencio, Cheryl (FNIH) [T] (b) (6) ; Colvis, Christine (NIH/NCATS) [E] [christine.colvis@nih.gov]; Desrosiers, Betsy [(b) (6) Hughes, Eric [(b) (6) Jansen, Kathrin (b) (6) Kurilla, Michael (NIH/NCATS) [E] (b) (6) Lowy, Douglas (NCI) [(b) (6) Read, Sarah (NIH/NIAID) [E] [(b) (6) .gov]; Tountas, Karen (FNIH) [T] [(b) (6) Santos, Michael (FNIH) [T] [(b) (6) Adam, Stacey (FNIH) [T] [(b) (6) James, Stephanie (FNIH) [T] [(b) (6) Alvarez, Rosa Maria [(b) (6) Kim, Elizabeth [(b) (6) Tolman, Brett [(b) (6) Wachtel, Jonathan [(b) (6) Prabhavathi Fernandes (b) (6) ; Diamond, Michael [(b) (6) Rose Li [(b) (6) Dana Carluccio [dana. (b) (6) Lagos, Enrique (NIH/NCATS) [E] [(b) (6) Jonson, Samantha (NIH/NCATS) [E] [(b) (6) Gonzalez, Nina [(b) (6) Simon, Dina (NIH/OD) [C] [(b) (6) Burrus-Shaw, Cyndi (NIH/OD) [E] [(b) (6) Rodriguez, Robin D (b) (6) ; Dave Frankowski (b) (6)]; Baric, Toni C [ant (b) (6) Lowy, Douglas (NIH/NCI) [E] [(b) (6) .gov]; Florence, Clint (NIH/NIAID) [E] [(b) (6) Nancy Haigwood (b) (6) Stratton, Benjamin [(b) (6) Gadbois, Ellen (NIH/OD) [E] [(b) (6)]

CC:

Start: 7/22/2020 2:00:00 PM
End: 7/22/2020 3:00:00 PM

Recurrence: (none)

From: Menetski, Joseph (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5001AF52DC4A427EA3D34F1E072F8CB7-MENETSKIJP]
Sent: 11/1/2020 5:02:19 PM
To: Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp];
(b) (6) Hild, Sheri (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=edd7f1939fb94be3bf063f925ac15f02-hildsa]; (b) (6) m;
(b) (6) (b) (6) (b) (6) (b) (6)
(b) (6) Baric, Ralph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.email];
(b) (6) Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7adfcdb42cbb4014d9b26af30cc-jhewitt]; Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda];
(b) (6) (b) (6) (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf];
(b) (6) Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; Rao, Srinivas [(b) (6) Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Tomas Cihlar [(b) (6) Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA) [(b) (6) Punturieri, Antonello (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ca7f3106e5f24b5cb5e933c6ee7a6bc7-punturiera]; Charette, Marc (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7fa2baf951848b5bf1f76a049a0eca6-charettemf]; Fessel, Josh (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=294e2bb481d94b83a1917f15338dfe19-fesseljp]; I (b) (6)
CC: Diamond, Michael [(b) (6) Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Desrosiers, Betsy [(b) (6) Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Jansen, Kathrin [(b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Alvarez, Rosa Maria [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user706e5647]; Kim,

While not unanimous, more people were able to make the 5th at 10am. We will go over the discussion at the Executive committee meeting, future strategic topics and then our normal reviews.

Changing time for preclinical WG

Joseph Menetski is inviting you to a scheduled Zoom meeting.

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 5/29/2020 1:28:32 AM
To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; Bozzette, Sam (NIH/NCATS) [E] [(b) (6) Butterson, Joan [(b) (6) De Claro, R. Angelo (FDA/CDER) [(b) (6) ; Draghia-Akli, Ruxandra [(b) (6) Eisner, Mark [(b) (6) Gottesdiener, Keith [(b) (6) Hughes, Eric [(b) (6) Judy Currier [(b) (6) Kim, Elizabeth [(b) (6) LaVange, Lisa [(b) (6) Levy, Elliot [(b) (6) Mellors, John W [(b) (6) Menon, Sandeep [(b) (6) Parker, Ashley (NIH/OD) [E] [(b) (6) Patel, Naimish [(b) (6) Peppercorn, Amanda [(b) (6) Poole, Mike [(b) (6) Proschan, Michael (NIH/NIAID) [E] [(b) (6) Read, Sarah (NIH/NIAID) [E] [(b) (6) Santos, Michael (FNIH) [T] [(b) (6) Shen, Yuan Li (FDA/CDER) [(b) (6) Stein, Peter (FDA/CDER) [(b) (6) Wholley, David (FNIH) [T] [(b) (6) Buchman, Tim (OS/ASPR/BARDA) (CTR) [(b) (6) Collins, Sylva (FDA/CDER) [(b) (6)]; Amanda Peppercorn [(b) (6) Garner, Carl [(b) (6) Higgs, Elizabeth (NIH/NIAID) [E] [ehiggs@niaid.nih.gov]; Koroshetz, Walter (NIH/NINDS) [E] [(b) (6) .gov]; Timothy Burgess [(b) (6) Reineck, Lora (NIH/NHLBI) [E] [(b) (6)]; Aggarwal, Neil (NIH/NHLBI) [E] [(b) (6) ; Rosenberg, Yves (NIH/NHLBI) [E] [(b) (6) Goff, David (NIH/NHLBI) [E] [(b) (6) Brown, Jeremy (NIH/NINDS) [E] [(b) (6) Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadbois]; Culp, Michelle (NIH/OD) [E] [(b) (6) Jacqueline Kirchner [(b) (6)]
CC: Colvis, Christine (NIH/NCATS) [E] [christine.co (b) (6) Desrosiers, Betsy [(b) (6) Jansen, Kathrin [(b) (6) Kurilla, Michael (NIH/NCATS) [E] [(b) (6) Lowy, Douglas (NCI) [(b) (6)]; Young, John [(b) (6) Biggs, Mary [(b) (6) Butcher, Tina [(b) (6) Demarcus [(b) (6) Macone, Erin [(b) (6) Melencio, Cheryl (FNIH) [T] [(b) (6) Salathin, Carla [(b) (6) Tountas, Karen (FNIH) [T] [ktountas@fnihi.org]; Menetski, Joseph (FNIH) [T] [(b) (6) James, Stephanie (FNIH) [T] [(b) (6) Wachtel, Jonathan [(b) (6)]; Tolman, Brett [(b) (6) Alvarez, Rosa [(b) (6) Gonzalez, Nina [(b) (6) Dana Carluccio [(b) (6) Rose Li Central Account [(b) (6) Anderson, Margaret [(b) (6) Lucas Smalldon [(b) (6) Stratton, Benjamin [(b) (6) [(b) (6) Mollica, Linda /US [(b) (6) Qashu, Felicia (NIH/OD) [E] [(b) (6)]; Patterson, Amy (NIH/NHLBI) [E] [(b) (6) Rubin, Daniel B. (FDA/CDER) [(b) (6)]; Marston, Hilary (NIH/NIAID) [E] [(b) (6) Chen, Helen Q. [(b) (6) Wung, Peter /US [(b) (6) Hoots, W. Keith (NIH/NHLBI) [E] [(b) (6)]
Subject: ACTIV TX-Clinical Working Group Meeting #9
Attachments: ACTIV_TX-Clinical_Working Group Meeting Guide_20200604.pdf
Location: https://fnihi.zoom.us/ (b) (6)
Start: 6/4/2020 5:00:00 PM
End: 6/4/2020 6:00:00 PM
Show Time As: Tentative

Required Attendees: Bozzette, Sam (NIH/NCATS) [E]; Butterson, Joan; De Claro, R. Angelo (FDA/CDER); Draghia-Akli, Ruxandra; Eisner, Mark; Gottesdiener, Keith; Hughes, Eric; Judy Currier; Kim, Elizabeth; LaVange, Lisa; Levy, Elliot; Mellors, John; Menon, Sandeep; Parker, Ashley (NIH/OD) [E]; Patel, Naimish; Peppercorn, Amanda; Poole, Mike; Proschan, Michael; Read, Sarah; Santos, Michael (FNIH) [T]; Shen, Yuan Li (FDA/CDER); Stein, Peter (FDA/CDER); Wholley, David (FNIH) [T]; Buchman, Tim (OS/ASPR/BARDA) (CTR); Collins, Sylva (FDA/CDER); Amanda Peppercorn; Garner, Carl; Higgs, Elizabeth (NIH/NIAID) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Burgess, Timothy; Reineck, Lora (NIH/NHLBI) [E];

Optional Attendees: Aggarwal, Neil (NIH/NHLBI) [E]; Rosenberg, Yves (NIH/NHLBI) [E] (b) (6)
Brown, Jeremy (NIH/NINDS) [E]; Gadbois, Ellen (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]; Jacqueline Kirchner
Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas
(NCI); Young, John; Biggs, Mary; Butcher, Tina; Demarcus; Macone, Erin; Melencio, Cheryl (FNIH) [T]; Salathin, Carla;
Tountas, Karen (FNIH) [T]; Menetski, Joseph (FNIH) [T]; James, Stephanie (FNIH) [T]; Wachtel, Jonathan; Tolman,
Brett; Alvarez, Rosa; Gonzalez, Nina; Dana Carluccio; Rose Li Central Account; Anderson, Margaret; Lucas Smalldon;
Stratton, Benjamin; (b) (6) Mollica, Linda /US; Qashu, Felicia (NIH/OD) [E]; Patterson, Amy
(NIH/NHLBI) [E]; Rubin, Daniel B. (FDA/CDER); Marston, Hilary (NIH/NIAID) [E]; Chen, Helen Q.; Wung, Peter /US;
Hoots, W. Keith (NIH/NHLBI) [E]

Dear ACTIV TX-Clinical WG,

Please find attached the slides for tomorrow's meeting which contain the agenda. We will be using this meeting as last week to update on the progress of the master protocol groups and the mAb subteam from the Agent Prioritization group.

Please let us know if there is anything else you feel the team needs to discuss.

Thanks,
Stacey

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From: Santos, Michael (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AB38CB6836DE44E18EF4CC6952F65F80-SANTOSMR]
Sent: 11/6/2020 6:01:03 PM
To: Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr];
(b) (6) Lowy, Douglas (NIH/NCI) [E] [(b) (6)]; (b) (6)
Arvin, Ann [(b) (6) Beth Bell ((b) (6) [(b) (6)]
(b) (6) Cavaleri Marco [(b) (6) (b) (6)
(b) (6) (b) (6) Greg Glenn [(b) (6)
(b) (6) Haynes, Barton [(b) (6) (b) (6) (b) (6)
Marks, Peter (FDA/CBER) [(b) (6) Mascola, John (NIH/VRC) [E] [(b) (6)
Messonnier, Nancy (CDC/DDID/NCIRD/OD) [(b) (6) Nelson Michael [(b) (6)
Offit, Paul [(b) (6) (b) (6) Seals, Jonathan (OS/ASPR/BARDA)
[(b) (6) (b) (6) (b) (6) Tal Zaks
[Tal. (b) (6)
CC: btolman [(b) (6) (b) (6) Hopps, Markay [(b) (6)
Kozlowski, Mary (NIH/NCI) [C] [(b) (6) Johnson, Maureen (NIH/NCI) [E]
[(b) (6) (b) (6) Jeneffer Haynes [(b) (6)];
(b) (6) (b) (6) (b) (6) Austin, Sarah (NIH/NIAID) [E]
[(b) (6) .gov]; (b) (6) Isabel Ramsey [(b) (6) Parker,
Ashley (NIH/OD) [E] [(b) (6) Marston, Hilary (NIH/NIAID) [E] [(b) (6)]; Erbeling,
Emily (NIH/NIAID) [E] [(b) (6) Dieffenbach, Carl (NIH/NIAID) [E] [(b) (6)
Qashu, Felicia (NIH/OD) [E] [felicia. (b) (6) Culp, Michelle (NIH/OD) [E] [(b) (6)]; Gadbois,
Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadbois]; Wholley, David (FNIH) [T]
[(b) (6) Melencio, Cheryl (FNIH) [T] [(b) (6) Menetski, Joseph (FNIH) [T]
[(b) (6) Adam, Stacey (FNIH) [T] [(b) (6) Tountas, Karen (FNIH) [T] [(b) (6)
James, Stephanie (FNIH) [T] [(b) (6) Colvis, Christine (NIH/NCATS) [E] (b) (6)];
Desrosiers, Betsy [(b) (6) Eric Hughes [(b) (6) Kurilla, Michael
(NIH/NCATS) [E] [(b) (6) Read, Sarah (NIH/NIAID) [E] [(b) (6) Paul Gillard
[(b) (6) François P Roman [(b) (6) : Hamilton, Holli (OS/ASPR/BARDA)
[(b) (6) Modjarrad, Kayvon CIV USARMY MEDCOM WRAIR (USA)
[(b) (6) Kathleen Neuzil [(b) (6) Martin, Stacey
(CDC/DDID/NCEZID/DVBD) [(b) (6)]; McNamara, Lucy Alexandra (CDC/DDID/NCIRD/DBD) [(b) (6)];
Schrage, Stephanie (CDC/DDID/NCIRD/DBD) [(b) (6) Verani, Jennifer R. (CDC/DDID/NCIRD/DBD)
[(b) (6) Lindsey, Nicole (CDC/DDID/NCEZID/DVBD) [(b) (6) Thornburg, Natalie
(CDC/DDID/NCIRD/DVD) [(b) (6) 'Wachtel, Jonathan' [(b) (6) Stratton, Benjamin
[(b) (6) Margaret Anderson [(b) (6) (b) (6)
(b) (6) Bethany Stokes [(b) (6) Kathleen Callahan
[(b) (6) Molloy, Delia (DPH) [(b) (6) Wood, Gretchen (NIH/OD) [E]
[(b) (6) Filip Dubovsky [(b) (6) Michael Watson (x)
[(b) (6) Antonio Lanzavecchia [(b) (6) Arvin, Ann
[(b) (6) Harris, Rebecca /SG (b) (6) ; Vivek Shinde [(b) (6)
Cohen, Myron [(b) (6) Criffield, Robin R. [(b) (6) Marovich, Mary
(NIH/NIAID) [E] [(b) (6) Young, John [(b) (6) Gonzalez, Nina
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d];
Jacqueline Miller [(b) (6)
Subject: ACTIV Vaccines Working Group meeting
Location: <https://fnih.zoom.us/> (b) (6)
Start: 11/11/2020 6:00:00 PM
End: 11/11/2020 7:00:00 PM
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Required	(b) (6)	Lowy, Douglas (NIH/NCI) [E];	(b) (6)	Arvin, Ann; Beth Bell
Attendees:	(b) (6)	(b) (6)	Cavaleri Marco; (b) (6)	
	(b) (6)	(b) (6)	Greg Glenn; (b) (6)	Haynes,
	Barton; (b) (6)	(b) (6)	Marks, Peter (FDA/CBER); Mascola, John (NIH/VRC) [E];	
	Messonnier, Nancy (CDC/DDID/NCIRD/OD); Nelson Michael; Offit, Paul; (b) (6)		Seals, Jonathan	
	(OS/ASPR/BARDA); (b) (6)	(b) (6)	Tal Zaks	
Optional	Tolman, Brett; (b) (6)	Hopps, Markay; Kozlowski, Mary (NIH/NCI) [C]; Johnson, Maureen		
Attendees:	(NIH/NCI) [E]; (b) (6)	Jeneffer Haynes; (b) (6)	(b) (6)	
	(b) (6)	Austin, Sarah (NIH/NIAID) [E]; (b) (6)	Isabel Ramsey; Parker,	
	Ashley (NIH/OD) [E]; Marston, Hilary (NIH/NIAID) [E]; Erbeling, Emily (NIH/NIAID) [E]; Dieffenbach, Carl (NIH/NIAID)			
	[E]; Qashu, Felicia (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]; Gadbois, Ellen (NIH/OD) [E]; Wholley, David (FNIH) [T];			
	Melencio, Cheryl (FNIH) [T]; Menetski, Joseph (FNIH) [T]; Adam, Stacey (FNIH) [T]; Tountas, Karen (FNIH) [T]; James,			
	Stephanie (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Kurilla, Michael (NIH/NCATS)			
	[E]; Read, Sarah (NIH/NIAID) [E]; Young, John; Paul Gillard; François P Roman; Hamilton, Holli (OS/ASPR/BARDA);			
	Modjarrad, Kayvon CIV USARMY MEDCOM WRAIR (USA); Kathleen Neuzil; Martin, Stacey			
	(CDC/DDID/NCEZID/DVBD); McNamara, Lucy Alexandra (CDC/DDID/NCIRD/DBD); Schrag, Stephanie			
	(CDC/DDID/NCIRD/DBD); Verani, Jennifer R. (CDC/DDID/NCIRD/DBD); Lindsey, Nicole (CDC/DDID/NCEZID/DVBD);			
	Thornburg, Natalie (CDC/DDID/NCIRD/DVD); Gonzalez, Nina; Wachtel, Jonathan; Stratton, Benjamin; Anderson,			
	Margaret; (b) (6)	(b) (6)	Bethany Stokes; Kathleen Callahan;	
	Molloy, Delia (DPH); Wood, Gretchen (NIH/OD) [E]; Filip Dubovsky; Michael Watson (x); Jacqueline Miller; Antonio			
	Lanzavecchia; Ann Arvin; Harris, Rebecca /SG; Vivek Shinde; Cohen, Myron; Criffield, Robin R.; Marovich, Mary			
	(NIH/NIAID) [E]			

Michael Santos is inviting you to a scheduled Zoom meeting.

Topic: ACTIV Vaccines Working Group meeting

Time: Nov 11, 2020 01:00 PM Eastern Time (US and Canada)

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To: Hild, Sheri (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=edd7f1939fb94be3bf063f925ac15f02-hildsa]; (b) (6)

(b) (6) (b) (6) (b) (6) (b) (6)

(b) (6) Ottinger, Elizabeth (NIH/NCATS) [E] [(b) (6) Hewitt, Judith (NIH/NIAID) [E] [(b) (6) Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda];

(b) (6) (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkera]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; Rao, Srinivas [(b) (6) Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA) [(b) (6)

Punturieri, Antonello (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ca7f3106e5f24b5cb5e933c6ee7a6bc7-punturiera]; Charette, Marc (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7fa2baf951848b5bf1f76a049a0eca6-charettemf]; Fessel, Josh (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=294e2bb481d94b83a1917f15338dfe19-fesseljp]; Isis. (b) (6)

Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm];

(b) (6) Baric, Ralph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.email]; Colvis, Christine (NIH/NCATS) [E] [(b) (6) (b) (6) (b) (6) Tomas Cihlar [(b) (6) Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcbcd42cbb4014d9b26af30cc-jhewitt]; Florence, Clint (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Mason, Stephen [(b) (6) (b) (6) (b) (6) Jacqueline Kirchner (b) (6); Graham, Barney (NIH/VRC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=171892ff532b4c208a546e6fc7e87b8a-bgraham]

CC: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabcd2247548e596778304f781f-austinc]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy [(b) (6) Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Jansen, Kathrin [(b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Alvarez, Rosa Maria [(b) (6) Kim, Elizabeth [(b) (6) Tolman, Brett [(b) (6) Wachtel, Jonathan [(b) (6) Prabhavathi Fernandes [(b) (6) Lagos, Enrique

(NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagosel]; Jonson, Samantha
(NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Gonzalez, Nina
[(b) (6) Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Burrus-Shaw, Cyndi
(NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Rodriguez, Robin D
[(b) (6) Dave Frankowski [(b) (6) Lowy, Douglas (NIH/NCI) [E]
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; Nancy Haigwood
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=03d589f440d84691ac0a530e4ba6ceb5-haigwoon.oh]; Stratton, Benjamin
[(b) (6) Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Melencio, Cheryl
(FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Diamond, Michael
[(b) (6) Rose Li [(b) (6) Dana Carluccio
[(b) (6) Baric, Toni C [(b) (6) Hawk, Harrison
[(b) (6) caroline. [(b) (6) Connelly, Sarah [(b) (6)
Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Ottinger, Elizabeth
(NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; FNIH
[(b) (6)]

Subject: Subgroup discussion of prediction of therapy resistance from emerging viral sequence data

Location: Zoom Meeting

Start: 11/18/2020 3:00:00 PM

End: 11/18/2020 4:00:00 PM

Show Time As: Tentative

Recurrence: (none)
every Wednesday from 10:00 AM to 11:00 AM

Required Attendees: (b) (6) (b) (6) (b) (6) (b) (6)
(b) (6) Tomas Cihlar; Graham, Barney (NIH/VRC) [E]; Hewitt, Judith (NIH/NIAID) [E];
Florence, Clint (NIH/NIAID) [E]; Mason, Stephen; (b) (6) Zahn, Roland [JRDNL]; Jacqueline Kirchner
Optional Attendees: Melencio, Cheryl (FNIH) [T]; Diamond, Michael; Rose Li; Dana Carluccio; Baric, Toni C; Hawk, Harrison;
(b) (6) Connelly, Sarah; Gadbois, Ellen (NIH/OD) [E]; Qashu, Felicia (NIH/OD) [E];
Ottinger, Elizabeth (NIH/NCATS) [E]; FNIH

From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 11/20/2020 8:52:11 PM
To: Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Draghia-Akli, Ruxandra [(b) (6) Eisner, Mark [(b) (6) Gottesdiener, Keith (b) (6) Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Kim, Elizabeth [(b) (6) LaVange, Lisa [(b) (6) Levy, Elliot [(b) (6) Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Menon, Sandeep [(b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Patel, Naimish (b) (6) Peppercorn, Amanda [(b) (6) Poole, Mike [(b) (6) Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Collins, Sylvia (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylvia.Collis]; Amanda Peppercorn [(b) (6) Garner, Carl (b) (6) Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Timothy Burgess [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=52e5e03dcbc847709eaab64457efa57e-TimothyBurg]; Reineck, Lora (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a62d88ba0c3b44e3bb922236c61304b3-reineckla]; Aggarwal, Neil (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c9de6615504ff9889f3b0c44a63526-aggarwalnr]; Rosenberg, Yves (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a5cb3e9a3a2747c38c42f68f5c8e40cf-roosenbey]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Brown, Jeremy (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce971eefec944a68a94add3b24835f5-brownj7]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Jacqueline Kirchner [(b) (6) Beigel, John (NIH) [E] [/o=ExchangeLabs/ou=Exchange Administrative

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CC: Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy [(b) (6) Jansen, Kathrin [(b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Young, John [(b) (6) Biggs, Mary [(b) (6) Butcher, Tina [(b) (6) Demarcus [(b) (6) Macone, Erin [(b) (6) Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Salathin, Carla [(b) (6) Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Wachtel, Jonathan [(b) (6) btolman [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user7b137a1e]; Alvarez, Rosa Maria [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user706e5647]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Dana Carluccio [(b) (6) Rose Li Central Account [(b) (6) Margaret Anderson [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab9a138f1e284c689fedfb10b8cc5295-marganderso]; Lucas Smalldon [(b) (6)]; Stratton, Benjamin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=usere3ed7188]; [(b) (6) Mollica, Linda /US [(b) (6) Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Marston, Hilary (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab30660917b942ffba9ae95d631116f3-marstonhd]; Chen, Helen Q. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user34aa917e]; Wung, Peter /US [(b) (6) Hoots, W. Keith (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=328221d5416d4fc59262c6c2eca59d4c-hootswk]; Groesch, Mary (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=69ab77a4c9bf499383186b9d9870344e-groeschm]; Shipp, Allan (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=16001e8ab49c4489aef107bd0ce27715-shippa]; Kindzelski, Andrei (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8bda5194bdca4d2594626f6313d2db5c-kindzelskia]; Hone, David M (Dave) CIV DTRA J9 (USA) [(b) (6) Reisler, Ronald B CTR USARMY DOD JPEO CBRND (USA) [(b) (6) Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Elsaid, Olivia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userf0efa7bd]; Walker, Paula (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fbe81b9b832e40acb5fd03b3cf32930-walkerp1]; Bethany Stokes [(b) (6) asorosa [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userffc6da86]

Subject: Summary of ACTIV Therapeutics-Clinical Working Group Meeting

Attachments: 2020-11-19_TX-Clinical_WG_Meeting_Summary.pdf

Dear ACTIV TX-Clinical WG,

Please find attached the summary of yesterday's call. Per Novartis' request, we have excluded the summary of their presentation. We would like to thank them again for their attendance and willingness to review their data with us.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
Foundation for the National Institutes of Health
Direct: (b) (6) | Mobile: (b) (6)
fnih.org
11400 Rockville Pike, Suite 600, North Bethesda, MD 20852



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From: Santos, Michael (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AB38CB6836DE44E18EF4CC6952F65F80-SANTOSMR]
Sent: 7/8/2020 3:05:26 AM
To: (b) (6) Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowy]; (b) (6) Arvin, Ann [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3bbf6108d53148f684dad333fce983de-aarvin.stan]; Beth Bell (b) (6) [(b) (6) (b) (6) Cavalieri Marco [(b) (6) (b) (6) (b) (6) (b) (6) Greg Glenn [(b) (6) (b) (6) Haynes, Barton [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5d4a05845b5b4069ad0447fb60ebfa79-hayne002.mc]; hotez@bcm.edu; (b) (6) Marks, Peter (FDA/CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b2e527bdba2b4a86b8d72f06b813d471-MarksP.fda]; Mascola, John (NIH/VRC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f78b40a596b4ca4a2850a429d1ae3f2-jmascola]; Messonnier, Nancy (CDC/DDID/NCIRD/OD) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=441f65db836c4a89a42aecb9a0d9b96c-NAR5]; Nelson Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7c3323ab6a02468689fa2c51a87c43cc-NelsonMicha]; Offit, Paul [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cdb9cc56fde4598a57b423d484dcf9f-offit.email]; (b) (6) Seals, Jonathan (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d7a87d49ccb4e3caaf5eb5d3586b1cc-Jonathan.Se]; (b) (6) Tal Zaks [(b) (6) (b) (6) Tolman, Brett [(b) (6) (b) (6) Hopps, Markay [(b) (6) Kozlowski, Mary (NIH/NCI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=15373a5a1d8a4fa89d49ba9c8561cc94-kozlowskimt]; Johnson, Maureen (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0cb4ad1bebe64791b0415a7eb4bf71db-johnsonr]; (b) (6) Jeneffer Haynes (b) (6) (b) (6) (b) (6) Austin, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=292fcb760f9f4f199ebe343e08ef1781-austinsj]; (b) (6) Isabel Ramsey [(b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Marston, Hilary (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab30660917b942ffb9ae95d631116f3-marstonhd]; Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

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[(b) (6) Hughes, Eric [(b) (6) Kurilla, Michael (NIH/NCATS) [E]
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(FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Read, Sarah (NIH/NIAID) [E]
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(FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Young, John
(b) (6) Paul Gillard [(b) (6) Hamilton, Holli (OS/ASPR/BARDA)
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=a28fc2f8eb134b00b5eaa4222d0576cc-Holli.Hamil]; Modjarrad, Kayvon CIV
USARMY MEDCOM WRAIR (USA) [(b) (6) Kathleen Neuzil [/o=ExchangeLabs/ou=Exchange
Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=33958e1252cf4266bffc8d94988f5715-kneuzil.som];
Schrage, Stephanie (CDC/DDID/NCIRD/DBD) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=9be29b344ba14363bdecaa43582ca226-ZHA6]; Verani, Jennifer R.
(CDC/DDID/NCIRD/DBD) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=7c249692151d46d6ac80cb28ada3d3a0-qzr7]; Thornburg, Natalie
(CDC/DDID/NCIRD/DVD) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=c8d079e00a5649639c6f1425f3bb075f-nax3]; Gonzalez, Nina
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d];
'Wachtel, Jonathan' [(b) (6) Stratton, Benjamin [(b) (6) ; Anderson, Margaret
[(b) (6) (b) (6) (b) (6) Bethany Stokes
[(b) (6) Kathleen Callahan [(b) (6) Molloy, Delia (DPH)
[(b) (6) Arvin, Ann [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=001a98d300d14b20b18c01181eb843e0-Arvinam.Sta]; Jacqueline Miller
[(b) (6) Kayvon Modjarrad [(b) (6)

Subject: Canceled: ACTIV Vaccines Working Group meeting

Location: Webex: <https://nih.webex.com/> (b) (6)

Start: 7/8/2020 5:15:00 PM

End: 7/8/2020 6:15:00 PM

Show Time As: Free

Required Attendees: (b) (6) Lowy, Douglas (NIH/NCI) [E]; (b) (6) Arvin, Ann; Beth Bell
(b) (6) (b) (6) Cavaleri Marco; (b) (6)
(b) (6) (b) (6) Greg Glenn; (b) (6) Haynes,
Barton; (b) (6) (b) (6) Marks, Peter (FDA/CBER); Mascola, John (NIH/VRC) [E];
Messonnier, Nancy (CDC/DDID/NCIRD/OD); Nelson Michael; Offit, Paul; (b) (6) Seals, Jonathan
(OS/ASPR/BARDA); (b) (6) ; Tal Zaks
Optional Attendees: Tolman, Brett; (b) (6) Hopps, Markay; Kozlowski, Mary (NIH/NCI) [C]; Johnson, Maureen
(NIH/NCI) [E]; (b) (6) Jeneffer Haynes; (b) (6) (b) (6)
(b) (6) Austin, Sarah (NIH/NIAID) [E]; (b) (6) Isabel Ramsey; Parker,
Ashley (NIH/OD) [E]; Marston, Hilary (NIH/NIAID) [E]; Qashu, Felicia (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E];
Gadbois, Ellen (NIH/OD) [E]; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Menetski, Joseph (FNIH) [T];
Adam, Stacey (FNIH) [T]; Tountas, Karen (FNIH) [T]; James, Stephanie (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E];
Desrosiers, Betsy; Hughes, Eric; Kurilla, Michael (NIH/NCATS) [E]; Read, Sarah (NIH/NIAID) [E]; Young, John; Paul
Gillard; Hamilton, Holli (OS/ASPR/BARDA); Modjarrad, Kayvon CIV USARMY MEDCOM WRAIR (USA); Kathleen Neuzil;
Schrage, Stephanie (CDC/DDID/NCIRD/DBD); Verani, Jennifer R. (CDC/DDID/NCIRD/DBD); Thornburg, Natalie
(CDC/DDID/NCIRD/DVD); Gonzalez, Nina; Wachtel, Jonathan; Stratton, Benjamin; Anderson, Margaret;
(b) (6) (b) (6) Bethany Stokes; Kathleen Callahan; Molloy,
Delia (DPH); Ann Arvin; Jacqueline Miller; Kayvon Modjarrad

To: Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Bascles, Lionel [(b) (6) Cohen, Myron [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2141b9e28c1a421fb3c1c4f75dd4c457-myron_cohen]; Corey, Larry [(b) (6) ; Desrosiers, Betsy [(b) (6) Dickens, Jim (NIH/NCATS) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12591c90404e46caba73079cf4a5e2ea-dickensj]; Doroshow, James (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a1d0fb9f055940c39b387cae2485faa6-doroshoj]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; King, James (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce1f3853e43d4463a04f7d74992f96ac-James.King.]; Kurilla, Michael (NIH/NCATS) [E] [(b) (6) Nayak, Seema (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=51d5ee6848004578b5bf9c808eca8f6f-nayaksu]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Payton, Manizhe (NIH/NIAID) [E] [(b) (6) Resnansky, Laura [(b) (6) Srinivasan, Badhri [badhri. (b) (6) Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Vincent, Mike [(b) (6) Wachtel, Jonathan [(b) (6)]; Garner, Carlos [(b) (6) Sizemore, Christine (NIH/FIC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=05494833e0fc47a9acac194cd338b201-csizemore]; Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]

CC: Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hughes, Eric [(b) (6) Jansen, Kathrin [(b) (6) Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Young, John [(b) (6) Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; Anderson, Margaret [(b) (6) Carluccio, Dana [(b) (6) Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Gonzalez, Nina [(b) (6) Heaton, Penny [(b) (6) James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Li, Rose [(b) (6) Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Tuveson, Nancy [(b) (6) Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Criffield, Robin [(b) (6) ; Minnich, Beth [(b) (6) Katz, Rebecca (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8e2b174d9bf748e9aa5ed901b4c5a3d9-katzrd]; Stratton, Benjamin [(b) (6) Tolman, Brett [(b) (6) Kenny, Dermot [(b) (6) pau [(b) (6) [(b) (6) [(b) (6) Haynes, Barton [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5d4a05845b5b4069ad0447fb60ebfa79-hayne002.mc]; [(b) (6) [(b) (6) Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; Marks,

Peter (FDA/CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b2e527dbda2b4a86b8d72f06b813d471-MarksP.fda]; Messonnier, Nancy (CDC/DDID/NCIRD/OD) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=441f65db836c4a89a42aecb9a0d9b96c-NAR5];
 (b) (6) Offit, Paul [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cdb9cc56fdb4598a57b423d484dcf9f-offit.email]; (b) (6)
 Seals, Jonathan (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d7a87d49ccba4e3caaf5eb5d3586b1cc-Jonathan.Se];
 (b) (6) (b) (6) Arvin, Ann [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3bbf6108d53148f684dad333fce983de-aarvin.stan];
 (b) (6) (b) (6) (b) (6) (b) (6)
 (b) (6) (b) (6) (b) (6) Johnson, Maureen
 (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0cb4ad1bebe64791b0415a7eb4bf71db-johnsonr]; Kozlowski, Mary
 (NIH/NCI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=15373a5a1d8a4fa89d49ba9c8561cc94-kozlowskimt]; Austin, Sarah
 (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=292fcb760f9f4f199ebe343e08ef1781-austinsj]; Victoria Davey
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c8291f38ec342f895243c0617e115ec-victoria.da]; Jintanat Ananworanich
 [(b) (6) Michael Watson (x) [(b) (6) Verani, Jennifer R.
 (CDC/DDID/NCIRD/DBD) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7c249692151d46d6ac80cb28ada3d3a0-qzr7]; Schrag, Stephanie
 (CDC/DDID/NCIRD/DBD) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9be29b344ba14363bdecaa43582ca226-ZHA6]; Marovich, Mary (NIH/NIAID)
 [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bfd0192d165d4643accf6347728dbaeb-marovichma]; Hamilton, Nancy
 [(b) (6) Mascola, John (NIH/VRC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f78b40a596b4ca4a2850a429d1ae3f2-jmascola]

Attachments: Clinical Trial Capacity Working Group Meeting Agenda_05122020.pdf

Location: [\(b\) \(6\)](https://zoom.us/j/ (b) (6))

Start: 5/12/2020 3:00:00 PM

End: 5/12/2020 4:00:00 PM

Show Time As: Busy

Recurrence: (none)

every Tuesday and Friday from 9:00 AM to 10:00 AM

Required Attendees: Bascles, Lionel; Cohen, Myron; Corey, Larry; Desrosiers, Betsy; Dickens, Jim (NIH/NCATS) [C]; Doroshov, James (NIH/NCI) [E]; Goff, David (NIH/NHLBI) [E]; King, James; Kurilla, Mike; Nayak, Seema (NIH/NIAID) [E]; Parker, Ashley (NIH/OD) [E]; Payton, Manzone; Resnansky, Laura; Srinivasan, Badhri; Stein, Peter (FDA/CDER); Vincent, Mike; Wachtel, Jonathan; Garner, Carlos; Sizemore, Christine (NIH/FIC) [E]; Qashu, Felicia

Optional Attendees: Colvis, Christine (NIH/NCATS) [E]; Hughes, Eric; Jansen, Kathrin; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Young, John; Adam, Stacey (FNIH) [T]; Anderson, Margaret; Carluccio, Dana; Cheryl (FNIH) Melencio [T] (b) (6); Francis Collins; Gonzalez, Nina; Heaton, Penny; James, Stephanie; Li, Rose; Menetski, Joseph (FNIH) [T]; Santos, Michael (FNIH); Tuvevson, Nancy; Wholley, David (FNIH) [T]; Criffield, Robin; Hamilton, Nancy; Minnich, Beth; Rebecca (NIH/NCATS) Katz [E] (b) (6) Stratton, Benjamin; Tolman, Brett; Kenny, Dermot; (b) (6) (b) (6) (b) (6)

(b) (6) Haynes, Barton; (b) (6)
 (b) (6) Lowy, Douglas (NIH/NCI) [E]; Marks, Peter (FDA/CBER); Mascola, John (NIH/VRC) [E]; Messonnier, Nancy (CDC/DDID/NCIRD/OD); (b) (6) Offit, Paul; (b) (6) Seals, Jonathan (OS/ASPR/BARDA); (b) (6) (b) (6) Arvin, Ann; (b) (6)
 (b) (6)
 (b) (6) (b) (6) (b) (6) Johnson, Maureen (NIH/NCI) [E]; Kozlowski, Mary (NIH/NCI) [C]; Austin, Sarah (NIH/NIAID) [E]; Davey, Victoria; Jintanat Ananworanich;

Apologies for the repeat emails, updated agenda is attached. Karen

Dear Colleagues, Attached is the meeting agenda. Looking forward to a robust discussion about vaccine protocols and capacity needs! Karen

ACTIV: Accelerating COVID-19 Therapeutic Interventions and Vaccines

Dear Clinical Trial Capacity Working Group members,

In anticipation of this working group making rapid progress on identified action items and other activities, the co-chairs have agreed that it will be important to hold twice-weekly calls to evaluate progress made by each subgroup, to identify areas of need, and to determine next steps. We ask that you make every effort possible to join each of these meetings, but understand that at times you may have competing priorities. To place a hold on your calendar, please accept this meeting invite with a response; later you can decline an individual meeting if you have a conflict.

An agenda and other meeting materials, as needed, will be distributed prior to each call.

With best regards,
Karen

Karen H. Tountas, PhD
Scientific Program Manager
Foundation for the National Institutes of Health

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To: Bozzette, Sam (NIH/NCATS) [E] [(b) (6)]; De Claro, R. Angelo (FDA/CDER) [(b) (6)]; Eric Hughes [(b) (6)]; Judy Currier [(b) (6)]; Mellors, John W [(b) (6)]; Parker, Ashley (NIH/OD) [E] [(b) (6)]; Proschan, Michael (NIH/NIAID) [E] [(b) (6)]; Read, Sarah (NIH/NIAID) [E] [(b) (6)]; Santos, Michael (FNIH) [T] [(b) (6)]; Shen, Yuan Li (FDA/CDER) [(b) (6)]; Stein, Peter (FDA/CDER) [(b) (6)]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [(b) (6)]; Collins, Sylva (FDA/CDER) [(b) (6)]; Higgs, Elizabeth (NIH/NIAID) [E] [(b) (6)]; Koroshetz, Walter (NIH/NINDS) [E] [(b) (6)]; Timothy Burgess [(b) (6)]; Reineck, Lora (NIH/NHLBI) [E] [(b) (6)]; Aggarwal, Neil (NIH/NHLBI) [E] [(b) (6)]; Rosenberg, Yves (NIH/NHLBI) [E] [(b) (6)]; Goff, David (NIH/NHLBI) [E] [(b) (6)]; Brown, Jeremy (NIH/NINDS) [E] [(b) (6)]; Culp, Michelle (NIH/OD) [E] [(b) (6)]; Beigel, John (NIH) [E] [(b) (6)]; Sizemore, Christine (NIH/FIC) [E] [(b) (6)]; Wholley, David (FNIH) [T] [(b) (6)]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Garner, Carl [(b) (6)]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Draghia-Akli, Ruxandra [(b) (6)]; Eisner, Mark [(b) (6)]; Gottesdiener, Keith [(b) (6)]; Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Kim, Elizabeth [(b) (6)]; LaVange, Lisa [(b) (6)]; Levy, Elliot [(b) (6)]; Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Menon, Sandeep [(b) (6)]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaa06ebd70-parkeras]; Patel, Naimish [(b) (6)]; Peppercorn, Amanda [(b) (6)]; Poole, Mike [(b) (6)]; Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Collins, Sylva (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylva.Coli]; Amanda Peppercorn [(b) (6)]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Timothy Burgess [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=52e5e03dcbc847709eaab64457efa57e-TimothyBurg]; Reineck, Lora (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a62d88ba0c3b44e3bb922236c61304b3-reineckla]; Aggarwal, Neil (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c9de6615504ff9889f3b0c44a63526-aggarwalnr]; Rosenberg, Yves